



Health & Fitness Supplements News

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Compliance Target: New Dietary Ingredients

Substantiation, Pre-Market Notification, List of "Acceptable Ingredients" *By Rick Collins, Esq.*

The dietary supplement industry is attracting heightened interest in Washington. Some game-changing legislative revisions are on the horizon. Meanwhile, the existing law is being enforced more aggressively than ever before, and companies that have failed to comply with the provisions of current laws and regulations may have a very rude awakening soon.

By way of background, pursuant to the Dietary Supplement Health and Education Act of 1994 (DSHEA), supplements are treated like foods, not drugs, because unlike pharmaceuticals the ingredients in supplements have already been in our diets and therefore have a built-in safety history. The law defines a "dietary supplement" as a product (other than tobacco) taken by mouth, that is intended to supplement the diet that bears or contains one or more of the following "Dietary Ingredients:" vitamins, minerals, herbs or other botanicals, amino acids, dietary substances for use by man to supplement the diet by increasing the total dietary intake (e.g., enzymes, organ tissues, glandular, and metabolites) or concentrates, metabolites, constitutions, extracts or any combination of those listed above.

Under DSHEA, dietary ingredients that were lawfully marketed as supplements prior to the 1994 amendment are given "grandfathered" status and don't require proof of safety or efficacy be submitted to FDA. But a "New Dietary Ingredient" (NDI) must meet additional requirements. A product containing a NDI is deemed adulterated (i.e., unlawful) unless it either 1) contains "only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered"; or 2) there is a "history of use or other evidence of safety" provided by the manufacturer or distributor to FDA at least 75 days before introducing the product into interstate commerce.

That brings us to what's going on today. It's these NDI's that are of great concern to those in Government. The Feds believe that some of the products on today's market either fail to meet the definition of a dietary ingredient or are otherwise adulterated NDI's. "The Tan Sheet" reported in January that at the request of the Senate Special Committee on Aging, the Government Accountability Office (GAO) had contacted several supplement marketers requesting information about their herbal extract products. GAO wanted to see evidence that the product was lawfully marketed prior to DSHEA, or proof that it contained only dietary ingredients in the food supply in

unaltered form, or a copy of notification and documentation provided to FDA showing history of use or other evidence of safety.

Even more aggressively, a growing number of Department of Justice prosecutors have begun investigating and even prosecuting companies for distributing allegedly adulterated NDI's. For example, the Government has just begun felony prosecutions in situations where products contain new synthetic ana-



Capitol Building; Washington D.C.

bolic steroids under the theory that the products don't meet the definition of a dietary ingredient or a dietary supplement and are instead "unapproved drugs" that are being fraudulently labeled and marketed as supplements. Note that the Government can prosecute these cases even if the company had previously stopped selling them. Companies concerned about this scenario should promptly discuss their options, including voluntary recall, with experienced legal counsel.

Senator John McCain announced in a February press conference that he plans to introduce new legislation called the Dietary Supplement Safety Act to amend DSHEA in several important ways, including by creating a list of "Acceptable Dietary Ingredients." Instead of FDA having to specifically ban an ingredient after it's on the market, marketers would need to seek approval before bringing something new or innovative to market. The draft bill also seems to toss out the idea of "grandfathered" ingredients in favor of this list, which presumably would be compiled from a review of registration documents supplied by the industry. The bill calls for every

dietary supplement facility to register its name, address, all trade names and a list of all dietary supplements "manufactured, packaged, held, distributed, labeled, or licensed by the facility." Every ingredient contained in each supplement must also be disclosed. And any reformulations or new dietary supplements would need to be updated in the registrant's registration.

Many of the bill's supporters, including all the big professional sports, the National Center for Drug Free Sport, and the U.S. Olympic Committee, are anxious to put an end to doping scandals tied to tainted supplements. Describing some sports nutrition supplement companies, Robert D. Manfred, Jr., Executive Vice President for Labor Relations of Major League Baseball said, "These unscrupulous supplement manufacturers intentionally exploit loopholes in the federal regulations by selling product containing drugs and marketing it as 'safe' and 'legal.' Congress needs to act now to close these loopholes." And the U.S. Anti-Doping Agency (USADA), another prime backer of the bill, has also been critical of the sports nutrition segment of the dietary supplement industry. "The McCain bill is a fair and balanced approach that provides significant protections for all consumers of dietary supplements, while at the same time avoids placing unreasonable burdens on legitimate companies in the industry," said USADA CEO Travis T. Tygart. "We are grateful to Sen. McCain for his strong leadership on this public health issue and urge other members of Congress to support this bill." The bill's supporters have a public initiative website at www.supplementsafetynow.com urging key revisions to DSHEA.

The draft bill is unlikely to pass without modifications. But the content of its provisions and the clout of its supporters, in combination with the GAO requests and the Department of Justice investigations and prosecutions, signal that NDI compliance has become a priority target for the powers in Washington. Clearly, even without some revision of DSHEA, the days of bringing New Dietary Ingredients to market without a solid DSHEA compliance package are over. The Government is taking the current law's NDI provisions seriously, and companies that rely on the "food supply" provision may do so at their peril. Marketers should be confident that their products comply with DSHEA before bringing them to market. Companies with products already on the market that may not comply with DSHEA should seek advice on obtaining a DSHEA compliance evaluation as soon as possible.

For a link to the full text of the draft bill and updates on issues of interest to industry, visit our blog at www.supplementcounsel.com/blog ■



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.



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 sub-

stantiation 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.

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

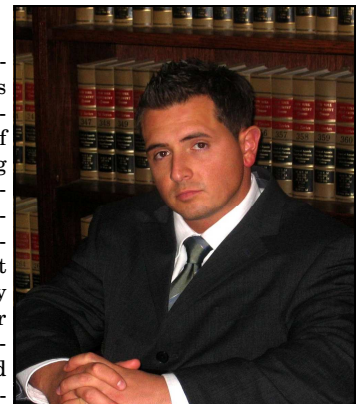
a misbranded and “unapproved new drug” that was implicated in a fatality. He is admitted to practice in both New York and Maryland.



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 GMP’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 an FDC and FTC standpoint (*FDA regulations deal with 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;
- Provide consultation on quality control measures and good manufacturing practices (GMP’s);
- 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;
- Provide consultation on drafting accurate and proper supplement fact panels;
- 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!