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Health & Fitness Supplements News

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Contaminated Supplements can be Costly: $578,000 Jury Verdict

By Marc Gann

In most sports, athletes who test positive for banned substances face stiff penalties ranging from monetary fines to suspensions to lost medals. In recent years, athletes have been quick to blame ingestion of a contaminated dietary supplement in an effort to defend their status and mitigate their punishment, usually to little or no avail. In fact, the United States Anti-Doping Agency (USADA) offers a guide to prohibited substances containing a warning that:

> *"Since anti-doping rules make the presence of a prohibited substance in an athlete's urine a doping offense regardless of how the substance got there, any athlete who takes a dietary supplement does so at his or her own risk of a positive test and a doping violation."*

Thus, athletes have been left with little recourse to mitigate their fine, suspension and the stigma that accompanies a positive doping test. It seems that athletes have begun to look to the courts to clear their name and recover what they have lost. In the case of competitive swimmer and Olympic hopeful Kicker Vencill, the company responsible for manufacturing the allegedly contaminated supplement, Ultimate Nutrition, was going to pay. Although the whopping jury verdict of $578,000 was ultimately vacated, a mutually agreed upon resolution was settled out of court.

More importantly, the claim brought by Vencill may have set a precedent for other athletes who are seeking retribution for a violation they claim is due to poor quality control in the supplement industry. Two professional tennis players have filed similar actions, one of whom successfully proved that a contaminated electrolyte product was the source of a positive test for the steroid nandrolone. These civil suits and allegations are a wake-up call to industry and a fitting segue for the introduction of the long-awaited supplement Good Manufacturing Practices (GMP's) that are expected by the end of 2005.

Contaminated supplements have allegedly caused athletes to test positive for banned substances.

Advertising, Labeling & Trademarks:

An interview with Alan Feldstein, Esq.

Why should companies selling supplement products care about legal issues involving advertising and marketing?

AF: They all advertise, don't they? Most supplement companies are very aware and concerned about the rules and regulations of the Food and Drug Administration (FDA), but they forget the fact that there is another government agency out there, the Federal Trade Commission (FTC), not to mention all the state regulations that govern how companies market and advertise their products. If companies are not careful, issues of marketing and advertising can cause more problems for them than FDA. FTC's job is to "enforce federal consumer protection laws that prevent fraud, deception and unfair business practices." In other words, anything that has to do with advertising or marketing a product, except for labeling (which is FDA's responsibility) falls under the jurisdiction of FTC. Therefore, what you say about a product, how you say it, and what support you have to make the statements you make, are all governed by FTC.

What is the greatest area of concern for a company when marketing a product?

AF: There are actually three. The first and most important is being able to substantiate your claims. If you are going to say your product improves performance by 25%, you better be able to prove that. Saying it that way would be dangerous because not everyone is going to have the same results with a product. What you say and how you say it will also determine precisely what form of substantiation you need. Some claims ("the world's greatest") may be deemed mere puffery and not have the requirement of substantiation. Another problem with substantiation that people get into is that they forget that even if your statement is absolutely true, if the net impression of your ad is false, you may still have problems. For example, if I have someone who has a PhD. in philosophy and I put her in a white lab coat and say this "doctor" recommends my product, the statement I am making is absolutely true. She is a doctor and she does recommend my product. However, because she is wearing a wearing a white lab coat I have given the net impression that she is some kind of doctor or scientist who has expertise to recommend my product. Thus, the net impression is false and I could be found in violation of numerous consumer protection regulations.

The second area is when companies create ads that compare their product to a competitor's. Comparative advertisements are very effective and in fact the FTC supports these ads because it helps inform consumers and assists them in choosing the best product for them. Where it gets tricky is how you compare your product to a competitor and what you say about the products. These types of ads especially, should have legal review before they are published.

The third area is what I call the intellectual property area. Whenever you hire outside, creative people to write copy, shoot pictures, or design logos, or when you hire models or other people to appear in your ads, you must make sure you have all the necessary rights. Let's say you obtained the right to use someone's photo in a magazine ad. Did you also get it for the packaging? In store displays? For use on your web site? **(Continued on Page 2)**

Interview Continued:

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What about your contract with the photographer? What rights did he grant you to use those photographs? Many companies get into trouble because they acquire certain rights and not others. Then after spending thousands of dollars in advertising space or packaging or web design, they find out they did not acquire the rights they needed. The area of intellectual property also involves clearing and registering trademarks and copyrights – something that CMG does a lot of. Companies must be prepared to not only obtain trademarks and copyrights, but also to invest in protecting those rights too.

"Then after spending thousands of dollars in advertising space or packaging or web design, they find out they did not acquire the rights they needed."

Isn't it expensive for all of this legal work? Is it worth it? Can't I just pull the ad if there is a problem?

AF: I tell all my clients – some of whom have learned the hard way – that you can pay us now or pay us later – it is always more expensive to pay us later. CMG likes working with entrepreneurial companies and is very fair in its billing practices. We do not have three lawyers all talking to one another about an issue and then triple billing. You get the right lawyer for the job. And yes, in certain instances you can just pull the ad, but most of the time that will not be enough. After the damage is done, getting you out of this mess will involve paying additional monies for additional rights (and by then you have no leverage to negotiate), fighting lawsuits or having to deal with the FTC, which may involve the payment of fines, running corrective advertisements and/or agreeing to refrain from certain advertisements. And all of that is very expensive – much more than if you had us review the advertisement in advance.

The bottom line is that in order to sell your product you must advertise. Great, creative advertisements can make a product a huge success. You just want to be sure, by having your advertisements legally reviewed in advance, that the profits from that huge success do not get eaten up by defending yourself from infringement claims or from false or misleading advertising claims by the FTC or your competitors.

Alan Feldstein, JD, serves Of Counsel to CMG, bringing with him extensive experience in advertising and marketing law specific to the dietary supplement market. Alan has counseled herbal supplement companies as well as fitness nutrition manufacturers, assisting with contracts, licensing, copyrights and trademarks, litigation supervision, claims substantiation and regulatory issues. He can be reached by telephone at (516) 294-0300 or by e-mail at info@cmgesq.com.

Supplement Facts

Serving Size 1 Capsule

Amount Per Capsule	% Daily Value
Calories 20	
Calories from Fat 20	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 4250 IU	85%
Vitamin D 425 IU	106%
Omega-3 fatty acids 0.5 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

FDA Word Jumble: DSHEA, NDI's & GMP's

Latest action targets Health & Fitness Supplements

By Rick Collins

The good news is that newly confirmed FDA Commissioner Lester Crawford believes in the Dietary Supplement Health and Education Act of 1994 and the premise that there is sufficient authority vested in FDA to enforce the Act. The bad news is that dietary supplement companies that have grown complacent with FDA's relative lack of enforcement action may be surprised by a reinvigorated effort to implement DSHEA. There is even Congressional legislation pending which would appropriate the monetary resources necessary to facilitate FDA's enforcement efforts.

Toward the end of 2004, FDA began to hold hearings and solicit commentary from industry and consumers regarding their upcoming proposals for New Dietary Ingredients and Substantiation of Label Claims. CMG's own Rick Collins and Alan Feldstein co-authored, *Comments on FDA's Pre-market Notification for New Dietary Ingredients*, which Mr. Feldstein presented to the Food and Drug Administration in Washington, DC. In November of 2004, FDA released a Draft Guidance document for industry regarding *Substantiation for Dietary Supplement Claims* under the Food, Drug and Cosmetic Act. Although the responsibility of monitoring dietary supplement advertising claims falls within the jurisdiction of FTC, FDA is responsible for monitoring the labeling of dietary supplements, which includes label claims. Therefore, both agencies share an interest in ensuring that all dietary supplement claims are supported by adequate substantiation. Although the recommendations in the guidance document were non-binding, they did describe the amount, type and quality of evidence FDA recommends a manufacturer have to substantiate that a claim regarding nutritional deficiency, structure/function, or general well-being is truthful and not misleading.

Then, in April of this year, FDA released another Draft Guidance, this time a *Dietary Supplement Labeling Guide* featuring eight chapters, one of which addressed *Pre-market Notification of New Dietary Ingredients* (NDI's). Although the labeling guide contained important FDA recommendations regarding label claims, content and layout, health & fitness supplement companies were primarily interested in the NDI information. The role of NDI's in the current supplement climate has been a highly controversial issue. Supplement companies that have attempted to file the 75-day pre-market notification have very often been disappointed with FDA's response. Some complain that if the relatively small percentage of approved NDI submissions continues, it will smother innovation in the industry. This has lead some companies to market supplements containing NDI's, that are potentially subject to FDA's enforcement power under DSHEA. CMG continues to guide our clients through the murky waters of NDI submissions, as we persist in our efforts to seek clarification and cooperation from FDA on the issue.

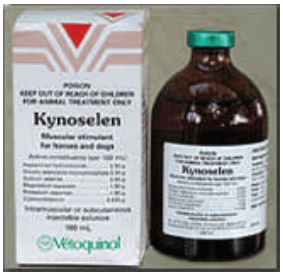
"GMP's...will facilitate FDA enforcement actions that were unavailable before."

The long-awaited dietary supplement Good Manufacturing Practices (GMP's) are due to be released by the end of this year, according to Commissioner Crawford. In a public speech on August 10th at the Drug Discovery Technology World Congress in Boston, Massachusetts, Crawford stated that the GMP's are in their final stages and their introduction will facilitate FDA enforcement actions that were unavailable before. It is anticipated that the introduction of supplement GMP's will have a profound effect specifically on the Health & Fitness segment of industry, as manufacturing practices have received little scrutiny during an unprecedented period of innovation and growth. CMG will keep you updated as each of these issues unfold.

Q & A with CMG: When Supplements Become Drugs

Q: When can the FDA claim that a particular dietary supplement is really a drug?

A (Rick Collins, JD): There's generally a *big* difference between supplements and drugs. However, while there *is* a line between the two, it *can* be crossed. A "dietary supplement" gets treated as a *food* and not as a drug, bypassing the FDA drug approval process, only if it meets certain requirements under DSHEA. It must be a product taken *by mouth* that contains certain "dietary ingredients" to supplement the diet, including vitamins, minerals, herbs, amino acids, enzymes and other dietary substances. If a product is designed for delivery as a topical gel or spray, it's *not* a supplement. Also, an ingredient which was approved as a drug before being marketed as a dietary supplement can *never* be used in a supplement, nor can any ingredient that's an "*unapproved new drug*."



The Veterinary Drug Kynoselen

Some products have been marketed as dietary supplements after being sold as drugs in other countries. Occasionally, FDA has exercised its enforcement power and deemed these products to be adulterated, misbranded, and unapproved new drugs. *Kynoselen*, for example, has been marketed online as a dietary supplement, and some adventurous consumers claim that it improves endurance and has anti-catabolic properties. However, it was designed to treat muscular dystrophy in horses and dogs. The only FDA-approved drug product that contains kynoselen is Ventipulmin®, a veterinary product used to treat horses that are not intended to be eaten. For humans, FDA has determined it to be a misbranded and unapproved new drug. A search of FDA's website (www.fda.gov) reveals an investigation regarding kynoselen in June of 2003, in which the owner of an Ohio-based veterinary company was convicted of introducing unapproved and misbranded drugs into interstate commerce via the Internet.

But it's not just the content of a supplement product that can remove it from the definition of a dietary supplement and turn it into a *drug*. What a supplement marketer *claims* about an otherwise legitimate product on the label or in advertisements can do it, too. These advertising claims are a common pitfall for supplement companies.

Products intended for use in the diagnosis, cure, mitigation, treatment or prevention of *disease* in man are drugs. A product sold as a dietary supplement and promoted on its label – or in accompanying materials used to market the product – as a treatment, prevention or cure for a specific disease or condition would be considered an unapproved – and thus illegal – drug. So-called "disease" claims – like "protects against cancer" – transform supplements into drugs. Even *implied* disease claims may be improper, such as naming a product "CarpalHealth" which could imply it prevents or treats carpal tunnel syndrome. Sometimes the difference between improper disease claims and legitimate body "structure/function" claims are extremely hard to discern. Supplement manufacturers and marketers must by law notify the FDA of structure/function claims made on their labels within 30 days of the product being marketed. They need to carefully review their labeling and ensure their products comply with DSHEA. Otherwise, they are risking FDA enforcement action.

Pills, Sprays and Orange Juice

By Alan Feldstein

The FTC puts its foot down on advertising claims

The Dietary Supplement Industry has come under increased FTC scrutiny in recent years. Together FDA and FTC have focused their attention on dietary supplement advertisements and label claims. The Federal Trade Commission (FTC) is responsible for regulating advertising claims, which includes print, broadcast, and Internet marketing materials. In cooperation with the Food and Drug Administration (FDA), FTC regulates the marketing of dietary supplements, protecting consumers from false and misleading advertising claims and enforcing laws outlawing "unfair or deceptive acts or practices."

As a preliminary issue, advertising claims must be truthful and not misleading and there must be adequate substantiation for all objective advertising claims. In addition to the individual claims, FTC will evaluate the "net impression" of an advertisement as a whole. It is important to note that dietary supplements are limited to structure/function claims, qualified health claims or authorized health claims. In order to use an authorized health claim you must obtain pre-approval from FDA. However, pre-approval is not necessary for structure/function claims.

FTC has targeted some of the many "fly by night" companies that market ineffective and sometimes fraudulent supplement products. Take for example the very popular Human Growth Hormone supplements. FTC has gone as far as to issue a Consumer Alert entitled, "HGH Pills and Sprays: Human Growth Hype?" FTC has stated that they have seen no reliable evidence to support the claim that these HGH "boosters" and "releasers" have the same effect as prescription HGH.

> *"Deceptive advertising practices can cost supplement companies millions of dollars."*

The most common pitfall that draws the attention of FTC is advertising claims that suggest or give the impression that a dietary supplement is intended to *treat* or *cure* a disease or medical condition. Deceptive advertising practices can cost supplement companies millions of dollars. In January of this year, Body Wise International settled State and Federal deceptive advertising charges for $3.5 million. In that case FTC alleged that Body Wise had made unsubstantiated claims that their product "AG-Immune" prevents, treats, or cures numerous diseases, including cancer, HIV/AIDS and asthma. In appropriate circumstances, FTC enforcement action has broadened to include ad agencies, distributors, retailers, catalog companies, infomercial producers and others involved in deceptive promotions, beyond the supplement manufacturer.

Even the largest companies are susceptible to costly advertising troubles. Just this past June, Tropicana settled FTC charges that it lacked the evidence necessary to substantiate the heart and stroke-related claims made in its' "Healthy Heart" juice. Lydia Parnes, Director of the Bureau of Consumer Protection was quoted as saying, "Orange juice contains many nutrients important to a healthy diet, and advertising can be an important source of information about the health benefits of foods. But it is essential that such advertising be truthful. In this case Tropicana's claims went well beyond its scientific support."

At CMG, we assist and encourage our clients to include only claims that can be substantiated by evidence consistent with FTC's standard of "competent and reliable scientific evidence," keeping in mind the meaning of the claim being made, the relationship of the evidence to the claim, the quality of the evidence and the totality of the evidence to support the claim.

Rick Collins, J.D.

Rick Collins practices primarily in the area of nutritional supplement law and sports drug defense. He 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. A former prosecutor, 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 nationally recognized as a foremost legal authority on anabolic steroids and steroid precursors, and has been the lead counsel or consultant in the defense of countless cases involving muscle-building or performance-enhancing substances from coast to coast. He is admitted to practice in the courts of New York, Massachusetts, Pennsylvania and the District of Columbia, and in various federal courts. Rick is the monthly legal columnist for *Muscular Development* magazine and the author of the groundbreaking book *Legal Muscle: Anabolics in America* (2002).

Alan Feldstein, J.D.

Alan Feldstein, an attorney based in Los Angeles and admitted to practice in California, serves Of Counsel to CMG. He is personally responsible for advising some of the firm's biggest clients in the nutrition industry, having served as general counsel for a dietary supplement company and part of the management team that took the company to over 150 million dollars in annual sales. Alan was also the catalyst for forming several industry coalitions to educate the public, legislators, and administration officials on supplement facts and science. He has extensive experience in assisting nutritional companies 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 serves on the adjunct faculty of Southwestern University School of Law, where he teaches advertising and marketing law. Known for his negotiating skills and business acumen, Alan's clients always appreciate his practical and insightful perspective on resolving legal issues affecting their bottom line.

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 can you expect from the soon-to-be-unveiled GMP's for supplements? 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 labels and advertising from an FDC and FTC standpoint (FDA laws 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 and good manufacturing practices;
- Provide general business advice;
- Advise and consult on various intellectual property issues including assisting clients in trademark and copyright registrations;
- Advise clients on State regulations, particularly regarding the sale and marketing of prohormones not listed in the new Anabolic Steroid Control Act;
- Advise clients on DSHEA compliance of "new dietary ingredients";
- 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 and class action lawsuits;
- 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.

Marc C. Gann, J.D.

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 dietary supplement ingredients including "New Dietary Ingredients" under the Dietary Supplement Health and Education Act. He has defended supplement marketers against federal criminal prosecutions, including the defense of an individual charged with the sale of a misbranded and "unapproved new drug" that was implicated in the fatality of a consumer. He has conducted jury trials on the toughest court cases, including the most serious criminal prosecutions (a high-profile double homicide, for example). While known as a very straightforward and especially persuasive negotiator, he has a reputation as a formidable adversary once litigation begins. He is also experienced in the defense of cases involving anabolic steroids, growth hormone and other bodybuilding drugs, and has defended and counseled anti-aging and hormone replacement medical clinics and compounding pharmacies. He is admitted to practice both in New York and Mary-