



Health & Fitness Supplement News

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DIETARY SUPPLEMENTS AND INTELLECTUAL PROPERTY: HOW CAN YOU PROTECT YOUR BRAND?

After spending countless hours building a business from the ground up—formulating a line of supplements, securing supplies, manufacturing and marketing products, and finally selling them—a supplement company wants nothing else but to succeed. But what can one do to stop others from using the company’s name to capitalize on its success? How can an owner protect her company’s slogans and ad copy against others who would like to use them? The solution lies in intellectual property law, which confers exclusive rights over the creations of one’s own mind.



Two main categories of intellectual

property are trademarks and copyrights. Our supplement clients often ask us whether they should trademark their materials, or copyright them. The answer depends on what the company is looking to protect.

A copyright is a type of protection afforded to authors of “original works of authorship,” including literary, artistic, dramatic, and certain other works, whether published or unpublished. While copyrights do not need to be registered, it is often advisable to file for registration since registrants receive some added statutory protection. Books, songs, and paintings are likely candidates for copyright protection. In the dietary supplement realm, copyright protec-

tion can extend to companies’ product labels. Additionally, advertising, like the claims a company makes about its product’s efficacy on labels, websites, and print ads, may be protected to an extent.

The amount of protection that copyrights offer is a difficult question in the world of commercial speech, however. So while one needs to advertise to achieve success, those advertisements may or may not be protected from copying by others. Moreover, a company’s ads may invite litigation over claims of copyright infringement. Finally, copyrights do not protect names, slogans, titles,



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FDA CRACKS DOWN AS INDUSTRY CONTINUES TO STRUGGLE WITH CGMPs

Under the 2007 supplement Current Good Manufacturing Practices (“CGMP”) final rule, manufacturers, packagers, labelers, and holders of dietary supplements must establish and follow CGMPs to ensure the quality of their supplements. However, as a rash of recent Food and Drug Administration (“FDA”) Warning Letters has demonstrated, many industry players are still failing to comply with the most basic CGMPs. In fact, in December 2013 alone, FDA issued four warnings to dietary supplement companies for CGMP violations. Moreover, Natural Products INSIDER reported that 70% of dietary supplement CGMP inspections result in FDA citations.

Supplement companies have been violating very basic, but very important CGMPs. For instance, three out of the four companies issued FDA Warning Letters last December failed to conduct any appropriate testing to verify the identity of any dietary ingredient prior to its use. These com-



panies trusted that the ingredients they received from their suppliers were the ingredients they ordered, which is an inexcusable practice in FDA’s view. Additionally, all four of the firms cited failed to establish specifications for the purity and strength of their products. Finally, each of the companies was found to have CGMP violations at the quality-control stage. These failures are troubling—rather than “mere” paperwork oversights, identity testing, establishing specifications, and quality control all weigh on the safety of the products that customers will consume.

Daniel Fabricant, the director of FDA’s Division of *(Continued on p.2)*

DIETARY SUPPLEMENTS AND INTELLECTUAL PROPERTY: *HOW CAN YOU PROTECT YOUR BRAND?*

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or logos. In sum, copyright protection may help guard a supplement company's marketing and labeling, but there are many gray areas for which legal counsel experienced in the intersection of intellectual property law and dietary supplements is necessary.

Trademark law helps to fill the gap left by copyright law in protecting names, titles, slogans, and logos. A trademark is a word, name, symbol, or device used in trade in connection with goods to indicate the source of the goods and to distinguish them from the goods of others. Trademarks are ideal for protecting a brand or product name—once a company trademarks its name, others cannot use that name or a confusingly similar name in connection with their own goods. And if they do, the trademark holder can sue the other for infringement.

Trademarks do not have to be registered with the U.S. Patent and Trademark Office, but there are many advantages that attach at registration. First, companies can register "intent to use" trademarks, which allows them to protect their brand name while they develop their products for use in com-

merce. Unregistered marks don't offer that protection—until it sells its products, a company must simply hope that the name it selected will not be used. Second, registered trademarks are recognized nationwide, while unregistered marks are generally only recognized in the area in which a company uses the name. So if a business is selling products exclusively in the Northeast, for example, a business in California may be able to use that company's unregistered trademark. Third, if a com-

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pany infringes on a registered mark, it is presumed valid and enforceable when the owner sues. However, the owner of an unregistered trademark must prove to the court that the mark is valid and enforceable.

Like copyrights, trademarks often involve tricky questions of law and business practice. In which class of goods should a company file its mark? If a trademark is filed in one class of goods, can a company regis-

ter the same trademark in another? Will a company be sued for using a name that is too similar to another firm's? If the Patent and Trademark Office files an Office Action tentatively denying a trademark, how should a company respond?

Collins, McDonald & Gann has a wealth of experience in the dietary supplements industry, representing a number of prominent, as well as start-up supplement companies. Part of what we do is handle our clients' intellectual property needs, striving to protect their brand and image to the maximum extent allowed by law. We research proposed trademarks, file them with the Patent and Trademark Office, and respond to any communications questioning the validity of the mark. We review labels and advertisements, advising companies on what they should and should not include, with the goal of preventing lawsuits and expense down the road. And if a company first comes to us after being issued an FDA or FTC warning for deceptive advertising or being served with notice of a lawsuit, we can help minimize the impact of the crisis.

Please call us any time at 516-294-0300 if you have any questions about protecting your brand, or if you have any other questions or concerns about dietary supplements.



FDA CRACKS DOWN AS INDUSTRY CONTINUES TO STRUGGLE WITH CGMPs

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Dietary Supplement Programs, has stressed that CGMP compliance remains FDA's top priority in the supplement arena. FDA is sure to continue to hammer home CGMP compliance during its inspections, and companies with inadequate specifications in



place should expect to be cited.

In addition to FDA action, a company ignoring basic CGMPs, such as testing the identity of its ingredients, should not be surprised by private litigation. Last year, supplement manufacturers made headlines when their products tested positive for anabolic steroids, prescription erectile dysfunction drugs, and other scheduled controlled substances. While some of this "spiking" may have been intentional, much of it was inadvertent. Tainted products not only invite regulatory action like FDA Warning Letters, but also pri-

ivate litigation and class action suits, which can be very costly for a company to resolve.

CGMP compliance is now, more than ever, essential to avoiding FDA enforcement and private lawsuits. While bringing your firm into CGMP compliance may seem like a daunting task, the lawyers at Collins, McDonald & Gann can help you along the path. With years of experience in FDA law, we can assist you in understanding your obligations and ensuring that you meet them. Call us any time at 516-294-0300.

THE FEDERAL TRADE COMMISSION'S NEW YEAR'S RESOLUTION: TAKE DOWN DECEPTIVE WEIGHT-LOSS SUPPLEMENTS

Just days into 2014, the Federal Trade Commission ("FTC") made headlines by announcing enforcement actions against four weight-loss companies. As a result of this so-called "Operation Failed Resolution," the companies—HCG Diet Direct, Sensa Products, L'Occitane, and LeanSpa—must pay a collective total of \$34 million to refund consumers who may have been misled by their ads. Among the products with unsupported weight-loss claims are the Sensa Weight-Loss System and L'Occitane's Almond Beautiful Shape and Almond Shaping Delight skin creams. Sensa's ads boldly proclaimed: "Lose weight without dieting"; simply sprinkle Sensa on your food, and you will feel fuller quicker. And L'Occitane promised that you could lose inches in just four weeks, simply by applying its skin creams. Unfortunately for the compa-

and reliable scientific evidence." Under FTC precedent, "competent and reliable scientific evidence" is defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." While this standard doesn't tell a company exactly what it needs to adequately support a claim, it does say something: No single document will meet the threshold of "competent and reliable scientific evidence." One animal study, one *in vitro* study, or even one double-blind placebo-controlled peer-reviewed study likely will not satisfy FTC. Companies should assemble a substantiation pack-



1. causes weight loss of two pounds or more a week for a month or more without dieting or exercise;
2. causes substantial weight loss no matter what or how much the consumer eats;
3. causes permanent weight loss even after the consumer stops using product;
4. blocks the absorption of fat or calories to enable consumers to lose substantial weight;
5. safely enables consumers to lose more than three pounds per week for more than four weeks;
6. causes substantial weight loss for all users; or
7. causes substantial weight loss by wearing a product on the body or rubbing it into the skin.

Collins, McDonald & Gann is staffed with FDA lawyers experienced in handling enforcement actions and lawsuits by FTC, FDA, the Better Business Bureau, district attorney's offices, and private litigators. We help supplement companies compile substantiation packages in response to FTC inquiries, but more importantly, we work with our clients from the outset to try to prevent any regulatory action from slowing their business and growth. Call us anytime at 516-294-0300 if you are facing FTC or FDA action, or if you'd like to know how to better avoid such problems. We're always here to help.

Despite the recent cries that dietary supplements are "unregulated," supplement companies know that they face enforcement from FTC, as well as the Food and Drug Administration ("FDA"), the Better Business Bureau, state district attorney's offices, and private litigators.

nies and their consumers, FTC found that the claims were false.

Despite the recent cries that dietary supplements are "unregulated," supplement companies know that they face enforcement from FTC, as well as the Food and Drug Administration ("FDA"), the Better Business Bureau, state district attorney's offices, and private litigators. Large and visible targets for these entities are a supplement company's advertisements—just ask Sensa Products.

To cover themselves and successfully fend off enforcement actions, supplement firms must be able to provide "substantiation" for each of their products' advertised effects. That is, each claim must be supported by "competent

and reliable scientific evidence," consisting of all the relevant support it can gather.

Fortunately, supplement companies in the weight-loss arena can avoid a future headache by taking a hint from FTC. In conjunction with its "Operation Failed Resolution," FTC released a guidance for broadcasters and publishers on how to assess weight-loss claims when evaluating advertisements for publication. The guidance, *Gut Check: A Reference Guide for Media on Spotting False Weight Loss Claims*, highlights seven claims that FTC's experts say simply cannot be true. A supplement company would thus do well to avoid saying that any product:

For industry news and updates, visit our blog 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 CGMPs?

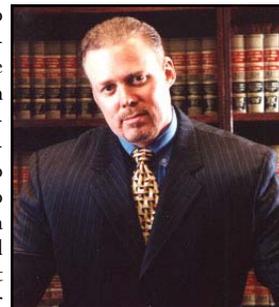
Collins, McDonald, & Gann, P.C. (CMG), is a law firm dedicated to helping clients in the health, fitness and nutrition communities. With recognized experts in sports performance supplements and regulatory, advertising and marketing law, CMG offers a powerful bi-coastal team providing a variety of legal services to a whole range of companies from start-ups to established organizations. 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). CMG can help you stay ahead of the curve!

- Are all your product names and other company intellectual property protected by trademarks?
- Can you fend off a challenge to any of your existing trademarks from a competitor?
- Have your dietary supplement product labels been reviewed by legal counsel?
- Do you have proper licensing and manufacturing agreements in place?
- Are you covered by adequate indemnification agreements?
- Could you survive a 483 inspection or an FDA investigation of your facility, products, labels or advertising copy?
- How do you navigate the maze of new dietary supplement FDA and FTC 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 the Dietary Supplement Health and Education Act (DSHEA)?
- How can you ensure your dietary supplement advertising complies with FDA and FTC regulations?
- How can you substantiate your claims or determine what claims are appropriate?
- Do you have sufficient studies and research to back up your claims?
- What must you, as a manufacturer, do in order to come into compliance with all Current Good Manufacturing Practices (CGMPs) for dietary supplements?
- Are you recording and reporting adverse events in accordance with the recently enacted Adverse Event Reporting (AER) system for dietary supplements?
- How do you handle risk management; do you have proper insurance coverage and procedures to deal with customer complaints?
- Have you been contacted by a District Attorney, State Attorney General, Better Business Bureau, Consumer Affairs department or the National Advertising Division (NAD) regarding substantiation of your claims?
- Have you received a Civil Investigative Demand from the FTC?
- Have you received a federal Grand Jury subpoena?
- Have you been served with a Class Action suit?

For industry news and updates, visit our blog at
www.supplementcounsel.com/blog

SELECTED FIRM PROFILES

Rick Collins, Esq. 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 Body-Builders. 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 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., 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.



David Torreblanca, Esq. joined CMG’s dietary supplement practice group in 2013, serving the legal needs of clients in the fields of sports nutrition, health, and dietary supplements. David earned a degree in psychology from Providence College, and he graduated *magna cum laude* from St. John’s University School of Law. He has a wide range of experiences, stretching from working under a New York State Supreme Court judge to interning with the U.S. Securities and Exchange Commission. Since graduating from law school, David has been immersed in the dietary supplement community, obtaining an in-depth understanding of FDA and FTC regulatory law.



Ellie R. Sladic, Paralegal, provides support to the attorneys of CMG and works extensively with dietary supplement trademark matters. She is a graduate from Suffolk County Community College’s ABA-approved A.A.S. Paralegal Studies program, where she graduated with Highest Distinction.

While at Suffolk County Community College, she served as president of the Legal Studies Club and was a member of Pi Alpha Sigma and Phi Theta Kappa Honor Societies, as well as Alpha Beta Gamma Business Honor Society. In addition, she was a recipient of the “Get There from Here” scholarship, a full academic scholarship.

Ms. Sladic is a licensed New York State Notary Public, a member of the National Association of Paralegal Assistants (NALA), and holds an A.A.S. in Advertising Art and Design as well.

