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Health & Fitness Supplements News

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What to Do When FDA Shows Up at Your Door

By Alan Feldstein, Esq.

Business is good. Orders are coming in and you are actually getting paid on time! You couldn't be happier. You decide to take the afternoon off. Then your cell phone rings. Your receptionist tells you that there are two FDA field agents standing in front of her and they are demanding to come in and inspect your premises.

You break out in a cold sweat. Your staff isn't prepared for a professional interrogation. You know you haven't done anything wrong, but you are concerned and are asking yourself, "Do I have a disgruntled employee? Because I didn't keep my counsel on retainer and stay in contact with him, am I unaware of a change in the law? Do I have to let the agents in? What have my employees said to them? What do I do?"

This article will give you a general idea of the do's and don'ts when inspectors show up. But first a caveat: this is not a comprehensive list. It's merely to give you an idea of some of the issues. Procedure manuals can run a dozen pages. This article is not a substitute for working with your lawyer on developing a comprehensive *standard operating procedure* that all your employees should be familiar with. If you don't have one, start working on one now.

FDA has the right to inspect all facilities at which food is manufactured, processed, and packed. This includes dietary supplements. Thus, you can expect "routine" inspections from time to time.

The areas which FDA may inspect are limited only to those facilities in which your product is manufactured and stored. This includes equipment, finished and unfinished materials, containers, and labeling. If FDA inspectors request, they can be given reasonable quantities of labels, regulated articles, and empty containers. You can bill FDA for product samples taken.

Also, you may be asked to review a document and asked to sign it or initial it. Don't, unless your lawyer says it is okay to do so. There is no statutory requirement for signatures, and the potential for misstating facts is great.

If an inspector shows up with a *search warrant*, then an entirely different procedure needs to be followed. There is the possibility that this is the beginning of a criminal proceeding and counsel should be brought in immediately. Do *not* attempt to resolve this matter yourself.

Most inspections should not be feared. It is FDA doing their routine job. What is important is to know how to react and how to identify those inspections that are not routine. If you have a policy in place and you know what to do, the next time you take the afternoon off you can do so without worrying what will happen if FDA shows up at your door. ■

Pulse of the Industry :

By Rick Collins, Esq.

An Interview with Eric Hillman, CEO of Europa Sports

RC: *This month we're interviewing one of the most influential and well-known names in Sports Nutrition, CEO of Europa Sports, Eric Hillman. At the helm of this phenomenally successful dietary supplement distribution company, Eric Hillman has a unique insight into the ever-changing market of dietary supplements.*

Do you feel that the sports nutrition market has changed over the last five years?

EH: Ideals and goals have remained basically the same. Products have changed as far as better actives and engineered ingredients. Example: bars today are more efficient and nutritious than 5 years ago and will continue to improve. When I began promoting sports supplements in 1986 at my gym in Winston-Salem, NC, there were three basic questions: 1) Does it make you big?; 2) Does it burn Fat?; and 3) Does it make you strong? Those three questions still dominate today, and in that same order of importance. As for a change, well, I think two things have changed. In regard to weight loss, people now want more energy and, thanks to Bill Phillips, we have more people interested in sports supplements than ever before.

What are the hottest product categories today, and what trends do you foresee for the future?

EH: Bars, protein powders, energy/fat burners and pre-workout supplements. The sports supplement industry is so much larger than the hardcore bodybuilder. It's more the transformation athlete that makes up the bulk of the sales. The difference is, a hardcore guy will go without *some* things, but he won't go without his supplements. To see the future, you need to look at the past. Like I said, the three main ideas will always be there. However as we live longer, I think the focus will be in a few different categories. Functional foods will be big ... easy to eat – for example, Muscle Milk Oatmeal, Muscle Milk and RTD's will only get bigger. The other category that I think will take over as the leader in all categories will be focus

Eric Hillman, CEO of Europa Sports / Courtesy of www.EuropaSports.com

memory products. As we get older and work longer it's going to take more focus to keep up in the workforce. A guy 45 to 50 years old who loses his job will find it harder to compete against the pay scale of a 25 to 35 year old. Mental and physical focus products will be big. Since we only use part of our brain, once we open the door to utilize more of it we will be unlimited in what we can accomplish. If you can focus on your workouts and maintain a positive thought process and full concentration, the physical potential can be unreal. I say learn how to harness those multi-tasking powers with a cognitive product and you will have more Einstein's and elite athletes running around than we previously could have imagined. By the way, I have A.D.D., though now they say I've graduated to A.A.D.D. (Adult ADD). Whatever you say doc.

(Continued on p.2)

Interview Continued:

From page 1

What message would you offer to consumers?

EH: Caveat Emptor (Buyer Beware)! At this point not everything is equal. Don't always buy because it's cheaper. We as an industry have to support the companies doing the research. Also look at what the product actually does – is it a pre- or post- workout product? Think about what your desired goals are and find products that will get you those results. Don't just take something because it's a hot product at the time. For example, if you're trying to trim down body fat, don't use a weight gain powder. You'd be surprised at how many consumers make such fundamental mistakes.

Having seen companies come and go, what characteristics do the most successful companies have in common?

EH: Like any industry, success comes with passion and foresight. The passion to be the best – along with the ability to be patient, surround yourself with the right people, constantly reinvest in your company, and do the proper research. In our industry, the manufacturers have got to realize it's the consumer that drives the demand. As a distributor you have to make sure you're doing your best to help the manufacturer get their product to the retailer the most efficient and profitable way possible for all three parties. Many of the unsuccessful manufacturers and distributors have relied on price instead, and they have hurt the industry.

What advice would you give start-up companies?

EH: Take up golf … just kidding. Put your money into the company and don't micromanage your associates. Hire the right people even if it means not taking a paycheck. My partner and I slept in parks during bodybuilding shows to save money. I drove a Mazda B210 4x4 pickup truck. We worked other jobs in order to buy inventory; I know many owners who drive big Mercedes' and have very nice houses, but struggle to get the things they need to grow their business. Remember, the consumer drives the demand. Make sure you have products they want and MARKET them. Don't give up on the marketing!

What do you say to those who call for more government regulation of the industry?

EH: Like any industry, there will always be ambulance chasers. They come and go, then maybe try to come back a few more times. As long as we're smart about the products we introduce and remember the importance of safety and the health of the consumer, our industry can continue to thrive. If companies stay on top of this and refrain from giving regulators the ammunition they're looking for, regulation will cease being the great storm cloud looming on the horizon that it appears to be. Let's all try to remember we're in the *health and fitness* industry.

> *"As long as we're smart about the products we introduce and remember the importance of safety and the health of the consumer, our industry can continue to thrive."*

What can industry do to protect the long-term interests of this market?

EH: We are in the process of doing it but it's been slow going and not organized. Be smart. Look past our noses. As I said before, we're here to promote "health and fitness." Educate the consumer. You have to be in this for the long haul. The average consumer and the media are ignorant as to what our industry truly is about. The misunderstanding surrounding ingredients like ephedra and prohormones are the first thing they think of. A misplaced ad by a greedy fly-by-night supplement company and a misinformed congressman can be very dangerous. We need to set our own standards of integrity and responsibility within the framework of what retailers and distributors will carry and what the magazines will advertise. I know of four different groups trying to do this. They should collectively be only one. It takes money to support these efforts and with all four lobbying for money, no one can get enough to make a dent. The sad part is, our industry won't talk to each other.

I see Europa as a pivotal player here since we deal with the manufacturers and store owners. We have the ability to get the info out faster than anyone else. Everyone wants us on their team but no one likes the idea when I tell them I will only do it as part of a single team effort. Who cares who gets the glory? If we can get the ball rolling soon, no one will be able to take this away from us. My idea is to get the major magazines to pull together and start working with the manufacturers to help fund our lobby through a small percentage of ad dollars. With only minimal individual contributions, the collective power generated by such alliances could go a long way to ensure our survival. Call me a dreamer … then again, that's how I got here in the first place ■

Industry Check-up: "Is my labeling compliant?"

By Mike DiMaggio, J.D.

As every company owner knows, creating a label for your dietary supplements can be a lot more complicated than making a list of the ingredients and slapping it on the bottle. Failure to comply with label requirements set forth by the Federal Food, Drug, and Cosmetic Act (FDCA) can leave you vulnerable to FDA regulatory action and both criminal and civil penalties. Labeling issues such as claims, warnings, substantiation, format, ingredient identification, listings, and classification are just some of the concerns you must take into account when creating a label for your product. Well, if FDA regulatory action wasn't enough of a concern, inadequate labeling issues can cost you major dollars due to fines and civil suits. Unfortunately, sometimes our clients come to us after it's too late and the damage has been done. So, here are some issues affecting labeling that *you* should be aware of in 2006.

Food Allergens

As of January 1, 2006, the "Food Allergen Labeling and Consumer Protection Act of 2004" (FALCPA) has changed the requirements for labeling foods which contain specific food allergens. FALCPA affects all food that is labeled on or after January 1, 2006, but does not require removal of products that were labeled prior to that date. Although not specifically indicated by FDA, as in the case of *trans* fats [see below], dietary supplement labels would likely be subject to these new requirements, as dietary supplements are classified as foods and currently subject to the same Good Manufacturing Practices (GMP's). It is clear that in some cases, dietary supplements may contain a "major food allergen" that is not obvious by looking at the label, and therefore poses the same risk to the consumer that the act is intended to protect against.

> *"...in some cases, dietary supplements may contain a 'major food allergen' that is not obvious by looking at the label."*

FALCPA is intended to address the nearly 150 individuals that die and the nearly 30,000 individuals that require emergency room treatment every year as a result of allergic reactions to foods. According to FALCPA, "a 'major food allergen' is an ingredient that is one of the following five foods or from one of the following three food groups or is an ingredient that contains protein derived from one of the following: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans." These food or food groups account for ninety percent of all food allergies. FALCPA requires, *(Continued. on p3)*

Industry Check-up Continued From page 2

amongst other things, more specificity in labeling. For example, in the case of nuts, the specific type of nut (e.g., almonds) must be indicated. In the case of fish, the specific species (e.g., cod) must be identified. Be aware that if you sell a product that may contain any one of the aforementioned allergens, your product label should comply with FALCPA.

Trans Fats

January 1, 2006 also marks the date after which "*trans* fatty" acids must be listed in the nutritional fact panel for conventional foods and dietary supplements. FDA issued its final rule on July 11, 2003, entitled, "*Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims." *Trans* fats, as they are commonly referred to, are made during partial hydrogenation of vegetable oils. This final rule is FDA's response to concerns about the effects of *trans* fats on raising low density lipoprotein-cholesterol (LDL-C) (i.e., "bad cholesterol") in the blood and the associated risk of developing coronary heart disease. The new labeling requirements are intended to provide consumers more information to assist them in following a healthy diet. Some quick labeling guidelines for dietary supplements are that you do not need to include a % DV for *trans* fats, listing *trans* fats should not change the amount of total fat as it is already included, and if the amount is less than 0.5 grams, it must not be listed on the label. FDA has received an overwhelming volume of requests for time extensions and continues to accept written requests from small businesses. Consult your attorney for questions on labeling of *trans* fats and guidelines for how requests for extensions of time to comply should be prepared.

California Proposition 65

Finally, you may have heard that dietary supplement companies have recently been slapped with civil suits alleging violations of California's Proposition 65, which is the "Safe Drinking Water and Toxic Enforcement Act of 1986." According to the Office of Environmental Health Hazard Assessment (OEHHA) website, the act was originally intended to protect California citizens and the State's drinking water sources from chemicals known to cause cancer, birth defects or other reproductive harm, and to inform citizens about exposures to such chemicals. Unfortunately, it seems OEHHA is more often being used as a tool to threaten huge civil penalties on unknowing manufacturers and distributors, resulting in huge monetary settlements that benefit private law firms. Currently, there is a pending Prop 65 lawsuit against dietary supplement companies alleging that certain products contain anabolic steroids listed under Prop 65 and that their labels fail to warn of the dangers of reproductive harm as required by the act. The dietary supplement companies named in the suit contend that their products do not contain substances listed under Prop 65 and are therefore not subject to the labeling requirements. State legislation is yet another issue that companies must be cognizant of when introducing products into interstate commerce, and yet another reason to have supplement labels examined and approved by knowledgeable counsel. ■

Hoodia: The Next Big Thing in Weight Loss?

By Alan Feldstein, Esq.

When ephedra initially went off the market, everyone – consumers, distributors, manufacturers and raw materials suppliers – scrambled to find a replacement. Numerous products hit the market, including bitter orange, green tea, guggulsterones, octopamine and various combinations of these and other ingredients.

Then a report by Leslie Stahl on the CBS program "60 Minutes" aired in late 2004. Her segment was a report from South Africa about a cactus-like plant called Hoodia Gordonii. This product has been used traditionally by the Bushmen ("the San") of Africa. When going out on long hunts, they would consume the cucumber-textured plant to help suppress their appetite and provide energy when out in the Kalahari Desert. Ms. Stahl tried some Hoodia right on camera and proclaimed that it suppressed her appetite. A new industry was born! Hoodia was the salvation for the weight loss products category – or was it?

How does Hoodia work? The active compound is P57. This compound was isolated and was studied by Pfizer for the potential development of a drug that could be used for weight loss. For reasons unknown, Pfizer abandoned its rights. According to several news reports, a company in England has now patented the Hoodia extract for weight loss and has made a deal with Unilever to include it in products starting in 2008. Supposedly, royalties from these sales will be shared with the San people – a rare occurrence for indigenous people who have developed effective treatments and remedies through natural plants and compounds.

> *"...the challenge is not so much about competition but rather about the limited amount of Hoodia available."*

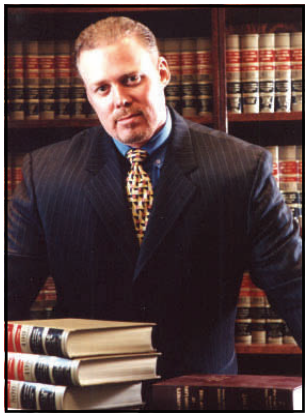
So should *you* be coming out with a Hoodia product? Well, as with most any question (especially one asked of lawyers), the answer is not a simple yes or no. The answer is, "it depends." There are several factors for you to consider.

First, if the patent is valid and Unilever releases a bunch of products it may begin trying to enforce its' patent rights. A problem for them is that the floodgates are already open. Search for "Hoodia" and you will see thousands of sites and a myriad of products for sale.

Second, while there are lots of Hoodia products being sold, the challenge is not so much about competition but rather about the limited amount of Hoodia available. This is not a product that is grown widely on a commercial basis. Thus, if you are going to come out with a Hoodia product, you better have great confidence in your raw material suppliers and make sure that they are supplying you with not only actual Hoodia, but the right species of Hoodia and an effective extract.

Third, Hoodia's weight loss potential is different from ephedra and its replacement products. Those products raise metabolic rate which helps burn more calories – i.e., burn more calories and you probably will lose weight. Hoodia works differently. It suppresses appetite, so that after you consume Hoodia you don't feel hungry.

Finally, as with any product you market, be sure you have the science to back up your claims. Your labels should properly inform the consumers about any potential side effects and that the amount of Hoodia you put in your product is an effective amount. Finally, have your labels and advertising reviewed by legal counsel. As always, "an ounce of prevention is worth a pound of cure." ■



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 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 serves on the adjunct faculty of Southwestern University School of Law.

Mike DiMaggio, J.D.

Mike DiMaggio is a graduate of St. John's University School of Law in Jamaica, New York. He has a comprehensive knowledge of the sports nutrition market and is an integral part of CMG's support staff. Having worked as a finance director for the Democratic Party, he has a firm grasp of the political process and its realities and has applied his knowledge to his work for CMG. He has also 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.

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 contraindictions;
- 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.