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Health & Fitness Supplements News

Volume 2, Issue 1 — A Journal for Industry from CMG — Spring / Summer 2007

FDA Inspection and Regulatory Action Update: By Mike DiMaggio, J.D.

As we discussed in our previous installment of this newsletter, 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.

In recent months, FDA investigators from district offices around the country have been visiting dietary supplement manufacturers and distributors and performing "routine inspections" of their facilities. These inspections have sometimes resulted in warning letters being sent to both manufacturers and distributors alleging numerous regulatory violations related to a variety of products. Some of the warning letters include allegations of labeling violations, misbranding, and allegations of false, misleading and unsubstantiated marketing claims. The most common allegation is that certain dietary supplements are not supplements at all, but are actually "adulterated" or "unapproved new drugs." This kind of determination by FDA has been based on a variety of reasons such as an analysis of the ingredients in a product, the purported method of delivery, and sometimes even the marketing claims made about the product. Most recently, FDA has begun to send warning letters to companies that fail to appropriately list food allergen warnings on their products. Companies that receive these warning letters are often instructed that they have (15) fifteen working days in which to respond to FDA with certain requested information and an explanation of how they will correct the alleged violations.

Recently, a particular category of sports and fitness supplements has come under FDA scrutiny, and many companies that sell these products have either been visited or received warning letters challenging their status. Although there has been no uniform determination made by FDA about these products, some FDA district offices have suggested that some of these ingredients are New Dietary Ingredients ("NDI's"), for which a 75 day pre-market notification should have been submitted. If these ingredients are in fact new dietary ingredients, then the only alternative to complying with the pre-market notification provision is if the ingredient is found in the food supply as an article used for food, without chemical alteration. Companies that are marketing products containing NDI's, should have either previously submitted pre-market notification or should have a substantiation package prepared that establishes an ingredients' compliance with DSHEA.

Companies that are visited by FDA investigators performing routine inspections should request a Form 482 and should know what materials investigators are entitled to and what areas they are entitled to inspect. Working with experienced legal counsel who can provide you with a Standard Operating Procedure for FDA inspections can eliminate some of the anxiety and uncertainty that can accompany these kinds of regulatory visits as well as protect your rights and your company's proprietary information ■

SCIENTIFIC SUBSTANTIATION : Protecting Your Investment By Rick Collins, Esq.

An Interview with David H. Schwartz, Ph.D. of Innovative Science Solutions, LLC

Q: What kind of services does Innovative Science Solutions offer to dietary supplement companies?

A: Innovative Science Solutions ("ISS") offers a variety of scientific support services to the healthcare industry that are particularly suited to the needs of the dietary supplement industry. Together, our team of scientists (e.g., chemists, biologists, physiologists, toxicologists) and regulatory experts work to assist companies in bringing products to market that are compliant with FDA and FTC regulations. We also provide the information and substantiation to assist these organizations in responding to inquiries and challenges to products that are already on the market. For example, ISS works with supplement companies' legal counsel to assist in evaluating and preparing substantiation packages prior to introducing products to market to ensure that they comply with the relevant regulatory requirements. This process often involves a close, "hand-in-glove" integration with counsel to provide the scientific basis for a rigorous legal analysis.

Above: David H. Schwartz, Ph.D.
Head, Liability Support Practice
Innovative Science Solutions, LLC

Q: Can Innovative Science Solutions assist in substantiating new dietary ingredients?

Yes, absolutely. ISS can also coordinate with legal counsel to prepare New Dietary Ingredient ("NDI") notifications, which must be submitted to FDA 75 days prior to introducing a new dietary ingredient to the marketplace. In addition to working with ingredients that companies may have already developed, ISS can also work with companies to develop and formulate products with new ingredients that are DSHEA compliant.

Q: Why is it important for a dietary supplement company to have a substantiation package prepared for the ingredients in their products? *(Continued on p.2)*

Interview Continued:

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A: Dietary supplement companies that have this kind of a package prepared for their ingredients are equipped to respond to current and future regulatory scrutiny. Given the risks and potential liability that can result from marketing a non-DSHEA compliant ingredient, companies can avoid potential costs associated with product recalls, regulatory fines and in some cases restitution and even criminal liability. In addition to FDA scrutiny, companies may face inquiries from the FTC with regard to their advertising claims. Again, ISS can work to prepare the research and information necessary to substantiate advertising claims made about products and ingredients. This may involve gathering all available literature on an ingredient or it may go as far as ISS developing a clinical, animal, or toxicological study of a product or ingredient, upon which future claims may be based. Again, ISS will coordinate with legal counsel to develop the substantiation that will allow companies to have confidence that their advertising claims and marketing materials are compliant with FTC regulations.

> "In addition to FDA scrutiny, companies may face inquiries from the FTC with regard to their advertising claims."

Q: Can ISS help companies that are concerned about the safety of their products and ingredients?

A: Yes. Obviously substantiating a dietary supplement products claims is only half the battle – compiling the available data to confirm the product's safety is also a critical component of a manufacturer's responsibility. ISS can help to evaluate the safety of dietary supplement products by examining the available scientific data supporting the safety of particular ingredients in isolation and in combination, as formulated in the product. When this type of information isn't available in the scientific literature, ISS can work with companies to conduct independent studies to determine the safety of ingredients, which can play a role in assessing the risk of marketing potential ingredients as well as developing product warnings and marketing materials.

> "Evaluating whether an ingredient meets this criterion of DSHEA is a complicated combination of law and chemistry."

Q: Can you talk about some of the work that you've done with our firm?

A: Sure. ISS has worked with CMG to assist clients in both responding to regulatory inquiries as well as evaluating new ingredients for regulatory compliance prior to introducing a new product to the marketplace. In some instances, CMG has requested that ISS search for all available data to substantiate that a particular ingredient is found in the food supply as an article used for food in a form that has not been chemically altered. Evaluating whether an ingredient meets this criterion of DSHEA is a complicated combination of law and chemistry. ISS gathered all relevant data and then analyzed that research to determine what, if any, literature supported the argument that a particular substance was DSHEA compliant. This information provided the groundwork for CMG's legal analysis of the substance's regulatory compliance and the basis for CMG's response to FDA. On the flip side, some of CMG's clients have proactively sought out a substantiation package accompanied by safety data for a particular ingredient. This not only leaves the client prepared in the event of regulatory scrutiny, but it provides a basis upon which marketing and advertising claims can be developed. For many ingredients, this type of information provides a reference upon which warning labels, serving sizes and intake recommendations may be based.

Q: Any final thoughts?

A: We at ISS believe in marketing safe and effective dietary supplements and we welcome the opportunity to continue to work with CMG and its clients to develop new ingredients and to substantiate and defend existing ones.

David received a Ph.D. in neuroscience from Princeton University and postdoctoral training in neuropharmacology and neurophysiology from the Center for Molecular and Behavioral Neuroscience at Rutgers University. He heads the Liability Support Practice at Innovative Science Solutions, having secured his reputation defending products in both legal and public settings. His work as a "scientific detective" helps clients defend and support dietary supplements in the courts, the regulatory arena and the market place. David's dietary supplement work is heavily informed by his extensive experience working with other healthcare products, including pharmaceuticals, medical devices, cosmetics, and foods. ■

"Account" for Yourself : An Interview with Ron Noreman, CPA

By Mike DiMaggio, J.D.

MD: *Recognizing the wide variety of issues that affect dietary supplement companies, this month we are pleased to bring you an interview with "Accountant Extraordinaire" Ron Noreman. First we will give you a little background history on Mr. Noreman and then we can delve into the questions.*

Ron is the partner in charge of taxation in the CPA firm Kamler, Lewis & Noreman in Great Neck, NY. He's one of two hundred CPA's nationwide who may practice in Federal Tax Court. He started his career at Price Waterhouse, the world's largest CPA firm and took the technical expertise acquired there and brought it to a smaller firm environment where client advocacy, street smarts, and tax reduction strategies are a regular part of their professional culture. In addition to having a highly diversified firm, which includes numerous nutritional supplement companies and professional athletes, he is a tax audit specialist with an over 94% win rate. Ron defines a win as when the IRS or other taxing jurisdiction ultimately settles on 50% or less than the amount of money they were originally seeking. Ron is also a competitive bodybuilder who's been lifting for over thirty years and has won numerous contest titles. He has also appeared on numerous radio shows on nutrition, formulated several antioxidant supplements for prominent vitamin companies and has counseled hundreds of individuals on nutrition for health and sports success.

> "If all operations are in one company, the whole entity is endangered by a legal action."

MD: ***What tax issues are particularly relevant to nutritional supplement manufacturers?***

RN: One of the most relevant and important issues is "Entity Layering," which also aids in asset protection. This technique is very powerful from both a tax and asset protection perspective at segmenting businesses into different entities with different purposes, product lines, and functions. The creation of two or more companies permits more "layers" of tax deductions and at the same time can shelter one company from being attacked in a lawsuit that affects another sister company. If all operations are in one company, the whole entity is endangered by a legal action. There are also segmenting techniques that can be used to *(cont'd on pg. 3)*

Ron Noreman Interview Continued From page 2

avoid taxation in multiple states. Another issue very relevant to nutritional supplement manufacturers are tax credits available to companies that use money to "create a product." The definition of "creating a product" makes the tax technique available to those who subcontract the manufacturing process out to others and also to those who physically manufacture in their own facilities. Tax preparers are often unaware of these potentially valuable tax benefits because they're believed to be only available to "brick and mortar" manufacturers. Finally, there are complex inventory rules that affect how the internal revenue service expects income to be recognized. This affects all companies that hold any amount of inventory. Further, there are additional rules regarding a partial disallowance of tax deductions for companies that produce inventory in their own facilities. These rules are a potential gold mine for the IRS and can cause costly audits if not competently addressed. Nine out of ten small accounting firms neglect or misunderstand this area of the law.

MD: ***You mentioned that nutrition companies can be taxed in multiple states; how does that occur?***

RN: All it takes is registering as a vendor at a trade show, for instance in Ohio, and if you sell anything, Ohio looks to tax you. Even if you don't sell anything, Ohio may be looking for an informational return. Additionally, having employees that perform work in states other than the home state of a given company will often get you taxed in more than one state. Finally, using company assets in more than one state can cause tax nexus as well. This is an area where planning with your tax advisor the manner in which you structure transactions will prevent inadvertent tax consequences.

MD: ***Any final thoughts?***

RN: A good CPA firm or tax advisor doesn't really cost money. We can often save clients many times the cost of our fees, take the drama out of the taxation process, and provide invaluable piece of mind.

MD: ***How can you be reached?***

RN: Ron Noreman, CPA; Kamler, Lewis & Noreman LLP, One Linden Place, Suite 200 Great Neck, NY 11021; (516) 829-0900.

MD: ***Thanks for your time and insight.*** ■

Industry Self-Regulation: Another Forum for Resolving Claims

An Introduction to the NAD and ERSP

By Alan Feldstein, Esq.

When most industry folks think of challenges to their advertising or label claims, they think of such things as Civil Investigation Demands from the FTC, a visit by an FDA inspector, or a letter from a State Attorney General or District Attorney. Yet there are other forums in which these challenges can take place. Those forums are industry self-regulation forums that allow competitors, when dealing with national advertisements, to resolve advertising disputes quickly, privately and in a cost effective manner.

There are two primary programs that affect the supplement industry. The first is the National Advertising Division of the Council of Better Business Bureaus (NAD). The second is the Electronic Retailing Self Regulation Program (ERSP) that is sponsored by the Electronic Retailing Association. The former deals with all sorts of advertisements, including dietary supplements. Their only requirement is that the advertisement be national. The latter addresses issues with products that are marketed via direct response to consumers.

Each program has its own procedures and processes for resolving disputes. One of the primary differences is that NAD deals with challenges to advertisements made by competitors. ERSP does that as well, but can also launch an inquiry on its own initiative if it comes across advertisements that it believes may be deceptive or misleading.

There are also similarities. Both procedures are private and confidential. Both are very quick – usually a matter can be concluded in 60 to 90 days. Because of the speed of the procedure it allows a company to have the issue resolved while the ad campaign is still running. Both are less expensive and time consuming than pursuing an action in court. Both are voluntary.

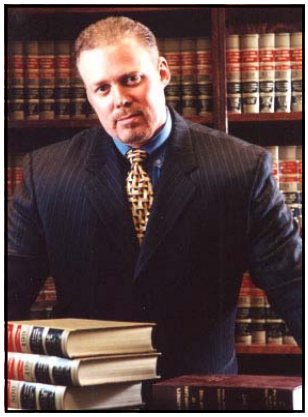
> *"Those forums are industry self-regulation forums that allow competitors, when dealing with national advertisements, to resolve advertising disputes quickly, privately and in a cost effective manner."*

Whether a competitor challenges an advertisement or whether the ERSP launches its own inquiry, the company which is the subject of the challenge will be given an opportunity to present any evidence it deems appropriate to respond to the inquiry. This is helpful and different from a judicial or regulatory procedure where certain evidence may not be considered. Thus in these types of challenges you can provide testimonials, consumer surveys, studies, customer service inquiries and other such evidence. In court or a regulatory environment this evidence may not be considered or may be discounted as to its value.

After that evidence is received there may be additional questions or requests for additional information that may be made. The goal is to resolve the dispute as opposed to being punitive. Thus many cases of this type are resolved by either there being no action taken or some adjustments to the advertising campaign being made.

While this process may not cause as much stress as a government inquiry it is still something that should not be taken lightly. Most importantly is should not be ignored. Both of these groups have a relationship with the FTC and other governmental agencies. The agencies appreciate the work these groups do as they can resolve matters without their involvement. However if someone chooses to ignore an inquiry from these self regulating bodies and refuses to participate then there is a substantial likelihood that the failure to cooperate will be brought to the attention of the FTC or other governmental agencies. Thus, while voluntary, there is incentive to participate.

Programs such as these are beneficial to companies as they resolve disputes and issues quickly and without risk of them spiraling into greater problems. However, they should not be handled without the benefit of counsel. A good lawyer knowledgeable in this area can help properly respond to any inquiry and assist in explaining not only the facts but the law in a clear and concise manner so that the inquiry is addressed and resolved without the need of further effort or expense.■



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 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.