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Good Manufacturing Practices: An Overview

By Alan Feldstein, Esq.

Regulations regarding good manufacturing practices (GMP's) have arrived. There is no escaping them (nor should you want to) and while some requirements may not be applicable to you, nevertheless you should be aware of them. The first thing you should be aware of is that these regulations are the law and can be enforced against you in court.

The goal of the GMP's is to establish the minimum GMP's necessary to ensure that, if you engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, you do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements.

The regulations are quite voluminous but a review of the subheadings in the regulations will give you an idea of the issues that you need to be aware of. Concern must be given to (a) maintenance of the physical plant where supplements and their components are manufactured and stored, (b) the procedures and maintenance of the physical equipment used to manufacture dietary supplements, (c) the kind of policies and procedures that must be in place in order to maintain proper records to verify and be able to audit the manufacturing process, (d) the kind of policies that must be in place in order to maintain proper quality control over the manufacturing process, (e) the kind of policies and procedures that must be in place regarding the labeling and packaging of dietary supplement products, (f) the records that must be kept during the manufacture of the products and each batch, (g) the way in which the storage of raw materials are handled and (h) the way complaints about products and the return of dietary supplement products are addressed.

Don't assume that because you are a marketer and distributor of dietary supplements who contracts with an outside manufacturer that you do not need to worry about these rules. In fact, the new GMP's actually expand the definition of manufacturer which will, in some cases, include distributors of dietary supplement products, subjecting them to the same kind of responsibility and liability attributable to the traditional manufacturer. The regulations were created to make certain that products are manufactured in a manner that ensures what your label states is in the product, actually is in the product, and that it does not contain any other ingredient or is manufactured in a way that poses a risk to the consumer. From a risk management perspective and to keep your business thriving (and out of trouble) meticulous quality control is something you should insist on from your manufacturer.

Thus when choosing a manufacturer you should ask important questions particularly as to how and from whom they get raw materials, the kind of testing they do on the raw materials, their manufacturing process, how they maintain their equipment and the records that they keep. You should also regularly inspect and have access to the facility to make sure that they stay compliant. Indemnification and insurance are also important things to have in place.

It does not matter how good your product is or how much product you can sell. If it is not made correctly, if contaminated raw materials are used, if it is not made in a manner to be able to verify each step of the manufacturing process or if you are not set up to handle consumer complaints, all your success will evaporate like fine powder in the air. In coming months small businesses should be familiarizing themselves with the new GMP's, and making their facilities and practices compliant with these regulations. Due to the voluminous and complicated nature of the document, companies should contact qualified legal counsel with their questions rather than rely on their own interpretation of the regulations. ■

TAINTED SUPPLEMENTS:

Straight Talk with Dr. Doug Kalman

By Rick Collins, Esq.

Dr. Doug Kalman is a recognized authority in the field of sports nutrition and dietary supplements. He has been involved in the industry as a counselor, researcher and from an academic vantage point as well. A Director in the Nutrition and Endocrinology division of Miami Research Associates (www.miamiresearch.com), Dr. Kalman sat down with me to discuss recent alarming media reports of contamination of dietary supplements.

R: Doug, many fitness and bodybuilding readers are familiar with your articles and column in *Muscular Development* magazine. You've been writing for *MD* for over ten years. Give us a little more on your background.

D: I have been involved in the clinical and applied research fields since the very early 1990's (Rockefeller University, Memorial Sloan-Kettering Cancer Center, Cornell Medical College, Peak Wellness and now MRA). My academic background is in nutrition (doctorate in exercise and nutritional biochemistry). The ISSN – International Society of Sports Nutrition (www.theissn.org) – is one society that I am very involved in as it is the *only* non-profit academic society dedicated to advancing the knowledge surrounding sports nutrition.

R: Tell us more about the study that was recently published finding that a whopping 25% of dietary supplements are tainted?

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Above: Douglas Kalman, PhD, RD, CCRC, FACN
Director, Nutrition & Applied Clinical Research
Miami Research Associates

Interview Continued:
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D: Recently a company known as HFL Limited (HFL Ltd.) out of Cambridgeshire, United Kingdom, released a report to the public detailing from their perspective potential contamination of dietary supplements with non-approved ingredients. HFL also has offices in North Carolina. Their finding that around 25% of the 55 products tested were tainted is somewhat surprising and can be read as a media cry for attention. I say that because while the supplement industry is instituting the FDA mandated Good Manufacturing Practices (GMP's) which will help to ensure better quality controls, the amounts of alleged contaminants found in the HFL study were minute – barely above minimal detection levels. Even more significantly, the amounts of contaminants did not appear to offer any physiologic impact. Most importantly, HFL failed to test whether someone who ingested one of the impure products would fail a test for banned substances. Until we know the answer to that question, we should view the HFL study as another paper in a long line of papers pushing the industry to better quality standards.

> "…the amounts of alleged contaminants found in the HFL study were minute—barely above minimum detection levels."

R: I agree: better quality control is an ongoing process. But what does this study say about current quality control and good manufacturing practices?

D: While I think we as consumers of products retailed by the supplement industry deserve to be able to purchase products of the highest quality, I do not think that the HFL study and report will have any long lasting effect. I suspect their hope is that manufacturers and finished product retailers would want to contract with their commercial arm (www.informed-choice.org) in order to have the products tested, and noted as being of quality and being free of banned substances. Again, I am not sure if the HFL report has such impact that we need to question quality control in the industry. We do not know if the products that they purchased for testing were on the market prior to any of the pro-hormones being banned or if the products would cause an athlete to fail a drug test. Simply put: if there's not enough of a substance to cause a positive drug test, then certainly there's not enough of the "bad" substance to have any significant physiologic impact.

R: What were the strengths and weaknesses of the methodologies employed?

D: The strengths of this study are the transparency with which HFL obtained samples and how they processed the supplements. The biggest offending compound found in the products was 1, 2 androstadienedione, with androstenedione coming in a close second. The weaknesses deal with the non-transparency of the products tested (products weren't named), and that in cases where one type of analysis revealed an inconclusive result but another method determined a positive result, the supplement was considered tainted. In reality, when you have one positive test and one inconclusive test, the whole should be thrown out and the tests repeated with the same supplement from a different lot.

> "I would recommend that the industry consider using third-party laboratories for evaluation of their raw materials and their retailed finished products."

R: Dietary supplements have been a favorite target of a few Capitol Hill folks. Is there anything that law-makers could take from this study?

D: Law-makers? Is this a loaded question? I hope that those on the Hill and those who represent the United States realize that the relatively new GMP regulations are now in effect, that they mandate an improved system for quality control, and that they hold people and companies responsible if they do not adhere to the rule. I believe that legislators should take home the message that Americans like and want their access to quality-of-life-oriented dietary supplements, and sports nutrition products are certainly just one segment of that category.

> "Consumers should always ask for and expect products of the highest quality…"

R: What's the take-home message for consumers?

D: Consumers should always ask for and expect products of the highest quality from whomever they choose to purchase them from. Consumers, especially those who are involved in the sporting world, should also seek to play by the rules of their organization and as such choose products from companies that have a five or 10-year track record in the marketplace. These companies have staying power for a reason.

R: What about industry? What would you recommend for supplement companies based on the study?

D: I would recommend that the industry consider using third-party laboratories for evaluation of their raw materials and their retailed finished products. There are only a few such certifications for these types of laboratories and one could get direction through the Natural Products Association on how to implement such a quality control program. I would bet that if a company posted or made available every Certificate of Analysis for each batch of finished product made for retail and made the CoA's publicly available, then their sales over time would increase as a result of increased confidence in the quality of the product.

R: Thanks, Doug. Your much-appreciated efforts to promote the ISSN (www.theissn.org) have helped spur its dramatic growth. It's a terrific group for sports nutrition industry folks to support and get involved with (the annual conference is scheduled for June 8th through 10th in Las Vegas). Supplement companies interested in consulting with you regarding their products should reach you by e-mail through Miami Research Associates at dkalman@miamiresearch.com.

Deadbeat Distributors By Daniel Russo, Esq.

When distributors don't pay their invoices, what is a manufacturer to do?

As is often the case in this industry, manufacturers and distributors have good personal relationships in addition to their business relationships. In fact, some companies operate without even drafting written contracts. That being the case however, this is a business and sometimes business and friendships just don't mix. One of the most common examples of this clash predictably revolves around money, more specifically, clients looking to collect payment for product shipped to distributors and never paid for. We attorneys refer to this as a "collection matter."

Our experience with these matters on behalf of our clients has shown that more often than not these outstanding balances are simply the result of an oversight on behalf of the distributor. In such cases, we can often resolve the matter with a letter and/or telephone call. What happens however when the recipient of the product disputes payment or simply refuses to answer our demand letter or telephone calls?

In such cases, we recommend a formula that we have had much success with in the past. We begin by choosing and contacting a local "collection" attorney in the same geographic area as the distributor. Once we are comfortable that we have chosen the right firm for the job, we coordinate the initiation of a lawsuit on behalf of the client by the local attorney. This includes gathering any and all information that the local attorney may need including evidence that the product was shipped by the client and received by the distributor.

Often being served with a lawsuit is sufficient for the creditor to be willing to settle the matter and the client will get most if not the entire balance due. However, when this is not the case, depending on the collection laws of the jurisdiction where the suit is brought, the local attorney may file for a default judgment. Absent proof on behalf of the distributor that the invoice was paid, the Court will often rule in favor of the client and the local attorney can have a judgment attached to the creditor's bank account effectively remove the amount of money due or place a lien on the distributors business.

While the process described above does take time, it often leads to our client getting their money with little cost and little hassle to the business at hand. Remember, it's not personal, just business. ■

Industry Self-regulation: Another forum for resolving claims

An introduction to the NAD and ERSP By Mike DiMaggio, 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.

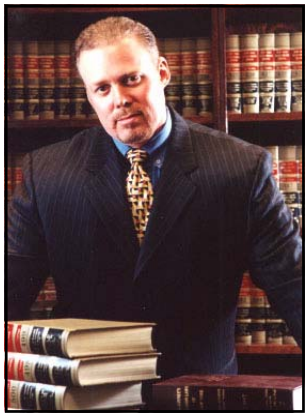
> "Those forums are industry self-regulation forums that allow competitors, when dealing with national advertisements, to resolve advertising disputes quickly, privately and in a cost effective manner."

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 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 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.

Mike DiMaggio, Esq.

Mike DiMaggio puts his comprehensive knowledge of the sports nutrition industry to work advising CMG's clients in the area of dietary supplement law, including FDA and FTC regulatory compliance and general business matters. He has served as the executive director of a supplement freedom trade group, directly interfacing with industry, other dietary supplement trade associations, Capitol Hill lobbyists, and members of Congress. He received his J.D. from St. John's University School of Law and is admitted to the New York State Bar and the United States District Court for the Southern and Eastern Districts of New York.

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.