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AVOIDING A GMP SHUT-DOWN BY FDA

Timely Action Now Can Save Money, Your Reputation … and Your Company

An inspection by FDA, for an unprepared dietary supplement company, can become a nightmare and can even lead to a shut-down of company operations – permanently tarnishing the brand, killing sales, and sometimes requiring expensive recalls or stock destruction, seizures and injunctions. FDA has announced it will implement more aggressive enforcement of Current Good Manufacturing Practices (GMPs), and the agency has already begun shutting down operations of dietary supplement companies that violate the regulations. **Robert Danko, Esq.**, is a California dietary supplement lawyer and GMP consultant with decades of experience in the supplement industry. Mr. Danko offered his thoughts on how to be prepared and how to avoid the regulatory nightmares that can result from GMP failures.

Q: Are most companies prepared for FDA inspections?

A: No. Companies need accurate legal and regulatory advice on GMP compliance *before* FDA inspectors show up at the door. They don't know how to handle an inspection, don't know their rights and responsibilities under 21 CFR Part 111, and only seek legal advice when it's late in the game – sometimes too late. Between two-thirds and three-quarters of such inspections result in the agency issuing GMP citations of varying degrees of seriousness. Waiting until inspectors are in your facility can be very costly.

Q: What are some common violations uncovered in FDA inspections?

A: A wide variety of failures in Standard Operating Procedures (SOP's) regarding quality control can render a product "adulterated" and illegal to sell. Failure to conduct identity testing is a huge problem, and the number one violation cited in recent FDA Warning Letters. Other examples include failure to establish proper laboratory control processes, insufficiently verified reference standard materials, flawed or non-existent written master manufacturing records, faulty batch records, and inadequate instrument calibration records. A company needs to be prepared and know what to do from the moment FDA shows up at the door until they leave. They need to be prepared for a very thorough inspection.

Q: What's the biggest mistake that companies make after an inspection?

A: Some companies either fail to respond to the Form 483 (which is the notice of violations) or try to do it themselves. Often they submit information too late, supply inadequate supporting documentation, and fumble their corrective actions. These faulty responses often result in FDA issuing a public Warning Letter to the company, which is a matter of public record that can sully the firm's brand and reputation. The companies and their owners can even run the risk of ending up the focus of a criminal investigation by FDA-OCI.

Companies need accurate legal and regulatory advice on GMP compliance before FDA inspectors show up at the door.

Q: What about brand owners who use contract manufacturers?

A: Even though you may have another company manufacturing (or blending, packaging or labeling) your product, you as the brand owner are still required to meet all the FDA regulatory requirements. You cannot assign this responsibility to a contract manufacturer. All brand owners must understand their regulatory obligations, or face the consequences when FDA comes calling.

Q: How can companies and their owners best protect themselves?

A: Get a GMP review and audit of your facility and put in place SOP's right now, before FDA inspectors show up. And don't just put those SOP's in your desk drawer. Make sure everyone is trained and knows what to do. Have your T's crossed and I's dotted in advance on all quality control and GMP obligations. Also, be sure to get legal review of all your product labels and advertising copy before they hit the market. Both FDA and FTC have become very active in scrutinizing dietary supplement materials, and FDA-OCI has even brought felony charges against company owners for making improper product claims. Good advice in advance can avoid a regulatory nightmare.

If you have questions on GMPs or on other regulatory matters, or if you would like to arrange a GMP review and audit with Robert Danko, call Collins, McDonald & Gann at 516-294-0300. Getting solid legal and regulatory advice upfront, before there's a problem, can save thousands of dollars and immeasurable stress.

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

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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?

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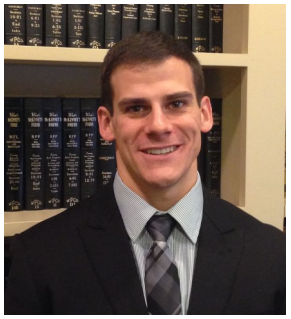
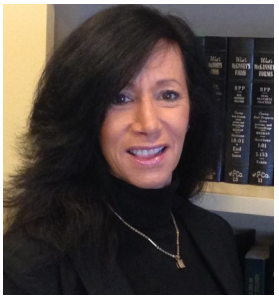
SELECTED FIRM PROFILES

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.

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