1990-2015 25th CMG ANNIVERSARY

COLLINS, McDONALD & GANN, P.C.
ATTORNEYS AT LAW

Celebrating 25 Years of Protecting Your Rights

Health & Fitness Supplement News

A Journal for Industry from CMG

Volume 11, Issue 3 Fall 2015/Winter 2016

FDA's (Not So) Secret Weapon: Current Good Manufacturing Practices

Current good manufacturing practices ("cGMPs") are essentially procedures set up by a firm to ensure the quality of its finished product. Based on our experience speaking with prospective clients, cGMPs are often the last thing on a supplement marketer's mind. Some don't even know what cGMPs are. However, failing to follow cGMPs can have dire consequences. Violations cause the product to be adulterated in the eyes of FDA and can trigger a recall of the entire product line, which can be very expensive. Courts, in conjunction with FDA staff, can even shut down a supplement brand for failing to comply with cGMPs.

At least six firms were enjoined from selling supplement products last year for cGMP-related violations.[1] FDA continues to voraciously pursue firms for not following cGMPs, and seemingly for good cause: between fiscal years 2010 and 2012, FDA cited seventy percent of the dietary supplement firms it inspected for cGMP non-compliance.[2]

In 2014, FDA issued at least seventy-one warning letters to dietary supplement firms,[3] many for cGMP reasons. FDA continues to issue cGMP warning letters. A fairly representative example is FDA's July 22, 2015 warning letter to Westar Nutrition Corp. d/b/a Viva Life Science, Inc. ("Westar"). Among other issues, FDA found that Westar failed to meet numerous cGMPs. For instance, FDA stated that Westar failed to provide documentation to support its determination that meeting specifications for Vitamin C and Calcium in a product would ensure that the specifications for other vitamins and minerals were met. Additionally, according to FDA, Westar failed to establish specifications for the identity of each component that is used in the manufacture of its dietary supplements, as required by 21 CFR 111.70(b)(1). FDA alleged that Westar also failed to comply with 21 CFR 111.70(g), which requires specifications for the labeling and packaging of the finished product. And the list goes on—you can read the full letter on FDA's website.

The Westar letter exemplifies FDA's heightened focus on cGMP compliance. This case is not an anomaly. Some violations may be due to ignorance. Ignorance is costly. A little time and counseling from an experienced cGMP attorney could have saved these firms a lot of money, time, and headache, and potentially even their businesses. Dietary supplement firms need to take action and stop overlooking cGMPs and expecting the government to do the same. Recent trends show that one of FDA's top priorities is cGMP compliance. As such, firms should be more vigilant than ever.

[1] http://www.gibsondunn.com/publications/pages/2014-Year-End-FDA-Compliance-and-Enforcement-Update-Food-and-Dietary-Supplements.aspx.
[2] http://www.naturalproductsinsider.com/news/2013/05/fda-gmp-inspectors-cite-70-of-dietary-supplement.aspx.
[3] http://www.nutraceuticalsworld.com/blog/blogs-and-guest-articles/2015-04-09/dietary-supplement-warning-letter-report-for-2014.

NY Attorney General Schneiderman's Continued War on Dietary Supplements

New York Attorney General (NYAG) Eric Schneiderman fired his opening shots to his War on Dietary Supplements in February 2015. Although those shots achieved a "win"—GNC agreed to make the changes that Schneiderman requested—his most recent move, a blitzkrieg on dietary supplement marketers using the ingredient "devil's claw," may be a dud.

On September 10, the NYAG issued thirteen cease and desist letters to dietary supplement marketers who used devil's claw in their products. The NYAG is claiming that the devil's claw supplements do not contain "devil's claw," which is the common name for the botanical *Harpagophytum procumbens* ("*procumbens*"), but instead contain *Harpagophytum zeyheri* ("*zeyheri*").

The NYAG claims that *procumbens* and *zeyheri* are different and that the latter is of cheaper quality. He found the discrepancy by relying on the same DNA barcode testing techniques deployed in February that some experts say is inappropriate for testing finished herbal supplements.

The American Botanical Council says that *zeyheri* is "a slightly different form of devil's claw, i.e., a different, but very close related species. In effect, they are like two siblings."[1] According to Thomas Brendler, a medicinal plant expert and editor of African Herbal Pharmacopeia, a technical book on African medicinal plants, "Both species of devil's claw have a similar chemical profile. While both species differ marginally in shape and chemical composition, both are considered equally effective."[2] Further, several government-recognized authorities list the two species as interchangeable for medicinal purposes.[3]

The NYAG refutes this argument by relying on a federal regulation that requires manufacturers to identify plant species using the common name standardized in the trade publication, *Herbs of Commerce*. But while that publication defines the common name "devil's claw" as *procumbens*,[4] the publication is not an exhaustive list and allows for amendments and additions to the text. Further, the version of Herbs of Commerce that is incorporated into federal law is over twenty years old.

There are legitimate safety issues within the supplement world, most of which FDA is addressing though ramped-up enforcement. Yet the NYAG has decided to attack marketers over what many consider to be semantics. Perhaps the NYAG will argue that the devil is in the details, but industry would suggest that he look instead into his testing methods and what he is trying to achieve.

[1] http://www.wholefoodsmagazine.com/nyags-attack-supplements-extends-devils-claw4538904
[2] http://www.naturalproductsinsider.com/blogs/supplement-law/2015/09/new-york-attorney-general-schneiderman-targets-de.aspx
[3] Id.
[4] https://www.longislandexchange.com/press-releases/a-g-schneiderman-issues-cease-and-desist-letters-to-13-makers-of-devils-claw-supplements-marketed-to-arthritis-sufferers/

HOW CAN CMG HELP YOU?

In the ever-changing landscape of the dietary supplement and functional food industries, you need to stay ahead of the curve. But how do you navigate a maze of regulations ... and run your business at the same time?

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 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 in the most cost efficient manner. 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 intellectual property protected?
- Have your product labels been reviewed by legal counsel?
- Do you have proper licensing and manufacturing agreements in place?
- Are you covered by adequate indemnification agreements?
- Are all your ingredients DSHEA-compliant?
- How can you bring a New Dietary Ingredient to market or obtain GRAS status?
- Do you have SOP's for recording and reporting Serious Adverse Events?
- How can you substantiate your claims to satisfy FDA, FTC, and other federal and state regulatory agencies?
- Do you have proper insurance coverage and SOP's for customer complaints?
- Have you received a Civil Investigative Demand from the FTC?
- Have you been served with a Class Action suit? How would you handle one?
- Could you survive a 483 inspection?
- Could you survive an investigation of your facility, products, labels or claims?
- Are you fully compliant with GMP's?

Selected Firm Profiles

Rick Collins, Esq., is based in New York and 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. He has defended dietary supplement and sports nutrition companies against claims of distribution of misbranded or adulterated products 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 numerous federal courts.

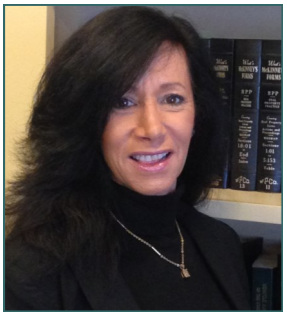
Alan Feldstein, Esq., an attorney based in Los Angeles and admitted to practice in California, serves Of Counsel to CMG. He is responsible for advising some of the firm's biggest clients in the sports nutrition industry and has extensive experience with contracts, copyright and trademark, label and advertising 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.

Robert Danko, Esq., is based in Southern California and serves Of Counsel to CMG. He concentrates his practice in the area of GMP regulations and FDA compliance. With decades of experience representing food and beverage manufacturers, he provides important legal guidance to CMG clients, including responses to 483 notices and FDA Warning Letters. A graduate of Pepperdine University in Malibu, he received his law degree from Western State University College of Law and has been a member of the California State Bar Association since 1988.

David Torreblanca, Esq., joined CMG's dietary supplement practice group to serve the day-to-day 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. David has an in-depth understanding of FDA and FTC regulatory law and excels at label and claims reviews.

Michael Bassett, Jr., Esq., is an associate lawyer at CMG focusing primarily on dietary supplement matters. He is a graduate of the Touro College Jacob D. Fuchsberg Law Center, where he served as a prominent member of the Criminal Law Society. He has handled a plethora of court cases throughout Long Island, where he also serves as a volunteer hockey coach and instructor for the Long Island Gulls ice hockey team.

Ellie R. Sladic, Paralegal, provides support to the attorneys of CMG and works extensively with dietary supplement trademark matters. She is a Highest Distinction graduate from Suffolk County Community College's ABA-approved A.A.S. Paralegal Studies program, attending on a full academic scholarship. Ms. Sladic is a member of the National Association of Paralegal Assistants (NALA).



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

ATTORNEY ADVERTISING

138 Mineola Blvd., Mineola, NY 11501 · Phone: 516-294-0300 · Fax: 516-294-0477 · www.supplementcounsel.com