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Trickle-Down Enforcement: Government Action Against Retailers Forces Brand Compliance

by David Torreblanca

In late 2016, GNC Holdings Inc. entered an agreement with the Department of Justice (DoJ) to pay the U.S. government $2.25 million and improve its compliance practices related to potentially unlawful dietary supplements. Under the non-prosecution agreement, the government agreed to not pursue GNC for selling products that allegedly violated the law. In exchange, GNC committed to bolstering its compliance measures to help ensure it sells only legal products. It may not simply rely on a supplement brand's assurances that a product or ingredient is legal.

Facing government pressure, other major dietary supplement retailers have stepped up their compliance efforts. In 2015, FDA warned five supplement marketers that the BMPEA ingredient in their products was not a "dietary ingredient." Weeks later, Vitamin Shoppe Inc. agreed with the attorneys general of Vermont and Oregon to cease selling BMPEA products. While Vitamin Shoppe had stopped selling these products before receiving notice from the attorneys general, its agreements with Oregon and Vermont carry penalties for breach.

The specter of government action seems to have led the remaining major retailers to scrutinize the

products they sell. For instance, Amazon.com has reportedly delisted a number of products containing the ingredient bitter orange fruit extract (30 percent synephrine). This action almost certainly flows from FDA's warning that it views bitter orange extract as a new dietary ingredient in need of a notification.

The threat—and reality—of regulatory action against retailers has created a trickle-down model of enforcement: Federal and state government pressure retailers to hold their vendors to the requirements of the law. Dietary supplement marketers cannot simply hope that problematic ingredients will go unnoticed by regulators. Retailers are on the front lines of enforcing regulatory requirements, and non-compliant brands cannot sell their products at major retail outlets.

Ingredient innovators and suppliers, and product formulators and marketers must carefully evaluate their ingredients to be sure they comply with all requirements of the law. Otherwise, a retailer may reject the entire run of products outright. The products would then be returned or destroyed at the supplement marketer's expense.

Finally, regulators' attention to retailers does not absolve dietary supplement brands of responsibility—or legal liability. FDA continues to target individual supplement companies (e.g., for selling 1-DHEA/1-Androsterone). And enforcement is not always limited to a warning. FDA and other government agencies may choose to investigate and prosecute both the retailer and the marketers of illegal ingredients. FDA and DoJ did just that to Bodybuilding.com LLC, its principals, and the brands that sold illegal products on the site a few years back. The Bodybuilding.com investigation resulted in numerous misdemeanor and felony convictions.

Please visit https://www.naturalproductsinsider.com/articles/2016/12/government-pressure-on-retailers-forces-complianc.aspx to read the full version of this article, published by Natural Products INSIDER®.

FDA Sheds Light on Establishing Intended Use of Products in Warning to Life Extension

by David Torreblanca

As (just about) every dietary supplement brand knows, supplements cannot be intended for the cure, mitigation, treatment, or prevention of disease. Companies making such "disease claims" about their products are illegally selling unapproved and misbranded new drugs. But will keeping disease claims physically (or digitally) separate from the products' webpages prevent FDA from considering them to be drugs? FDA's recent warning letter to Life Extension suggests the answer is no.

According to FDA, Life Extension Foundation Buyers Club, Inc. ("Life Extension") marketed its products for conditions that cause them to be drugs. FDA details its untangling the web of links, Facebook posts, website re-directions, and an e-book to allege that the products' intended uses are as drugs. For instance, it points to a chapter in Life Extension's e-book on brain tumors that references products and links to www.lifeextension.com, where consumers can purchase products. It suggests the physically separate claims in the book may be attributed to the products themselves—they inform the intended use of the products.

FDA warning letters are not law, but they signal FDA's thinking on topics. Considering the Life Extension warning letter, companies hyperlinking their dietary supplement products to separate materials on disease treatment risk FDA enforcement. FDA does not confine its claims inquiry to the four corners of a product page—it follows the links companies provide.

Unless Life Extension challenges FDA on the warning letter, it has a lot of work to do. FDA noted "there are over 400 products on your website that contain various disease claims."

If you have any questions about your marketing strategy, we are here to help. Call us with any questions at (516) 294-0300.

WHAT SERVICES DOES CGMB 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 Gann McCloskey & Barry, PLLC (CGMB), 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, CGMB offers a powerful bi-coastal team providing a variety of legal services to a whole range of companies from start-ups to established organizations. CGMB offers in-depth experience and personalized attention you can trust to get you the answers you need ... when you need them. The partners of CGMB 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). CGMB 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 cGMPs?

The best time to ensure compliance with the law is up-front, before there's a problem!

Feel free to call us at (516) 294-0300

CGMB - 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 CGMB. 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 trademarks, 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 CGMB'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. He regularly helps clients respond to FDA warning letters and threatened class action litigation.

Robert Danko, Esq., is based in Southern California and serves Of Counsel to CGMB. He concentrates in the area of cGMP regulations and FDA compliance. With decades of experience representing food and beverage manufacturers, he provides important legal guidance to CGMB 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.

For more information about CGMB, industry news and updates visit www.supplementcounsel.com.

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