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FDA WARNS AGAINST CBD

by David Torreblanca

In a set of 8 warning letters dated February 4, FDA warned cannabidiol (CBD) marketers against making disease claims and selling the products as “dietary supplements.” The alleged disease claims included claims to cure, mitigate, treat, or prevent conditions like rheumatoid arthritis, pain, schizophrenia, alcoholism, and a host of others.

Importantly, in six of the letters FDA reasserted its current position on the regulatory status of CBD as a supplement, writing: “You should be aware that, based on available evidence, FDA has concluded that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the Act [21 U.S.C. § 321(ff)(3)(B)(ii)].” Under that provision, a product containing a substance that has been authorized for investigation as a new drug for which substantial clinical investigations have been undertaken and made public is excluded from the definition of “dietary supplement.” FDA wrote CBD fits within this category. Moreover, FDA

believes that CBD does not qualify for the exception to section 201(ff)(3)(B)(ii). The exception provides a product containing such a substance may qualify as a “dietary supplement” if it was marketed for use in a food or supplement prior to the authorization of the new drug investigations.

The issue may not be settled. FDA concluded its warning letters by inviting the companies to provide more information: “FDA is not aware of any evidence that would call into question its current conclusion that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the FD&C Act, but you may present the agency with any evidence that has bearing on this issue.” Hector Lopez, MD, CSCS, FAAPMR, principal and co-founder of Supplement Safety Solutions and The Center for Applied Health Sciences, posits some companies have a strong case against the preclusion of agricultural hemp-derived CBD as a dietary supplement (or conventional food product). According to Dr.

Lopez, substantial clinical investigations may not have been instituted or made public prior to a CBD-containing hemp extract or other CBD-containing dietary ingredient being marketed and available in interstate commerce. If true, that could mean CBD may fit within the exception to section 201(ff)(3)(B)(ii) and be sold in supplement products. Either way, we expect to hear more on CBD in near future.

Call us with any questions at (516) 294-0300.



DIETARY SUPPLEMENT INSURANCE Q&A WITH GREG DOHERTY



Q: Why do I need product liability insurance in the first place?

A: Two reasons, which will motivate you to purchase it. First, so you can sleep at night knowing that if you are sued because your product allegedly injured someone, the insurance company you hired will pay for attorneys to defend you and the settlement costs of the lawsuit. Second, if you intend to do business with a retailer of any consequence you will have to show them evidence of product liability insurance.

Q: When I purchase a product liability policy, it will cover a product recall event, right? After all, it's called “product liability” insurance, so it should cover that.

A: No. A product liability policy was never intended to cover the numerous financial liabilities generated by a recall. Some of carriers put some “window dressing” product recall coverage in their policy, but don't be fooled. That coverage is subject to a sublimit of insurance, which will disappear quickly. And it only covers your direct costs, not the substantial costs that others will likely incur, will blame you for and will want reimbursement for. Separate, comprehensive product recall coverage is available in the insurance marketplace.

Q: Will it cover a class action, false advertising allegation or labeling violation from the FTC, FDA or a competitor?

A: No. Even though there is a coverage part in the policy called “advertising injury,” which might imply that coverage is afforded for false advertising claims, no coverage actually exists.

Q: I've heard there are certain ingredients that these insurance companies won't insure. Is that true and what should I do to make sure I'm fully covered?

A: Yes, it's true that each carrier has its own list of excluded ingredients, leaving you high and dry if a claim is made against you for a product with an excluded ingredient in it. First, be aware that these exclusions exist. Second, before you part with your money to buy a product liability policy for your company, make sure you review the exclusion list from the carrier your insurance provider is recommending, because all of the lists are not the same and they are constantly changing in the dynamic nutraceutical climate we live in today.

Greg Doherty is an Executive Vice President and Managing Director of the Dietary Supplement Practice Group for Bolton & Company Insurance Brokers of Pasadena, CA. Call Greg toll free at 844-677-2454, email him at gdoherly@boltonco.com or visit his website at www.gregdoherty.net.

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 GMP's?

*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 GMP 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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138 MINEOLA BLVD., MINEOLA, NY 11501 PHONE: 516-294-0300 FAX: 516-294-0477 WEB: WWW.SUPPLEMENTCOUNSEL.COM