

What Marketers Should Know About the Regulation of CBD-Based Products

The passage of the Agriculture Improvement Act of 2018, commonly known as the Farm Bill, removed hemp and all of its cannabinoids, including CBD, from the Controlled Substances Act. *Agriculture Improvement Act of 2018*, H.R.2, 115th Congress, § 1 (2018). However, excitement over the passage of this legislation was quickly tempered by the Food and Drug Administration's (FDA) statement that, under the Food, Drug and Cosmetic Act (FDCA), it remains unlawful to introduce hemp-derived CBD into food and beverages and to market CBD-based products as dietary supplements. CBD is an active ingredient in FDA-approved drugs and, under the FDCA, it is illegal to introduce drug ingredients into the food supply or to market them as dietary supplements absent prior approval.

Though the FDA recently assembled an internal working group to address questions left unanswered in its 2018 statement and to propose potential pathways for marketing and selling CBD products, such pathways do not appear to be forthcoming in the near future.

Notwithstanding FDA's current position on CBD, companies large and small have already brought to market myriad products, ranging from CBD-infused gummies to CBD capsules to CBD-containing pet treats. After all, CBD is big business and consumers are always searching for alternative remedies. In fact, it is anticipated that the CBD industry will grow to \$16 billion by 2025. *CBD Market Could Reach \$16 Billion by 2025, New Analysis Finds*, Fortune, by: Kristine Owram and Bloomberg, (Feb. 25, 2019). However, given the current regulatory landscape, those companies are at risk of enforcement actions by FDA and violations by state and local governments. And like marketers of all other products, the risk of product liability and consumer fraud lawsuits is ever-present. In order to mitigate against these risks, there are a few best practices that marketers of CBD-based products should consider.

Avoid Health Claims

At FDA's recent public hearing regarding CBD, acting Commissioner Dr. Sharpless emphasized that FDA's biggest concern is products claiming to prevent, diagnose, mitigate, treat or cure diseases, such as cancer, in the absence of requisite approvals. It is FDA's belief that such unapproved health claims may encourage patients and consumers to use CBD-containing products to treat serious and potentially fatal diseases at the expense of more traditional and approved therapies. It is therefore not surprising that FDA has been particularly aggressive in policing against unapproved health claims.

For example, the FDA recently sent warning letters to companies marketing dietary supplements containing CBD. In these letters, FDA admonished these companies for attributing health benefits to their CBD-containing products and claiming that they are effective for treating certain medical conditions, including combating tumors and cancer cells. These companies were advised to promptly take action to address these violations or FDA would consider taking further action without notice, including seizure of the offending products and/or the imposition of injunctions.

In order to steer clear of FDA enforcement proceedings and state and local regulatory actions, marketers of CBD products should consider avoiding health claims (i.e., that their products are capable of preventing, diagnosing, mitigating, treating or curing diseases). In addition to helping keep FDA at bay, avoiding the use of health claims will also mitigate against the risk of consumer fraud lawsuits challenging the scientific or factual veracity of representations made by marketers.

Always Have Claim Substantiation on Hand



Richard Fama

Member

rfama@cozen.com
Phone: (212) 908-1229
Fax: (866) 263-1334

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The Federal Trade Commission (FTC) enforces federal consumer protection laws that prevent fraud, deception, and unfair business practices. For products making health, safety, or efficacy claims, the FTC requires that advertisers possess “competent and reliable scientific evidence,” that means “tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and [that] are generally accepted in the profession to yield accurate and reliable results.” See, e.g., POM Wonderful LLC, 155 F.T.C. 56, 193 (2013), aff’d in part, 777 F.3d 478, 504- 05 (D.C. Cir. 2015), cert. denied, No. 15-525, 2016 U.S. LEXIS 2991 (May 2, 2016); Telebrands Corp., 140 F.T.C. 278, 347 (2005), aff’d, 457 F.3d 354 (4th Cir. 2006); Novartis Corp., 127 F.T.C. 580, 725 (1999), aff’d, 223 F.3d 783 (D.C. Cir. 2000); Brake Guard Prods., Inc., 125 F.T.C. 138, 256 (1998).

Prior to making **any** claims in the marketing and advertising of CBD-based products, including claims related to the products’ ingredients, potency, purity, and efficacy, marketers need to have evidence on hand supporting these claims. Such evidence will not only be useful if marketing claims are challenged by FTC but will also serve to mitigate against the potential for consumer fraud litigation. In short, all representations on the products’ packaging and advertising must be truthful and factually and scientifically verifiable.

Provide the Proper Product Warnings and Instructions

Apart from FDA regulatory concerns, marketers should keep in mind basic product liability principles. Specifically, marketers of CBD-containing products should consider warning consumers about the potential risks associated with use of their products and providing instructions on how to use them safely.

Examples of such warnings and instructions may include, but are not limited to, advising consumers: (1) to consult with a medical professional prior to use; (2) to discuss with a medical professional the medications (both prescription and non-prescription) that the consumer is presently or plans to be taking while using the CBD-based product; (3) to keep the products out of reach of children; (4) about proper storage of the product, e.g., in refrigerated environment; (5) and about any known potential side effects. Generally, warnings should be presented clearly on the packaging of these products so that they can be readily seen and understood by the average consumer.

Be Aware of State-Specific Regulatory Concerns

Knowledge of the laws of the specific states marketers wish to sell their products is also critically important. What may be legal under one state’s laws may be illegal under another. For example, Texas recently passed legislation that legalizes the production and sale of certain hemp products, including containing CBD. TX HB 1325. However, in Colorado, while CBD is a permissible food ingredient under that state’s laws, it remains unlawful to add CBD to pet food. It is therefore recommended that marketers consult competent legal counsel to advise them on the specific state laws that may be applicable to their particular products.

Contracts with Suppliers

Marketers of CBD-containing products will undoubtedly rely upon third parties for a variety of essential functions, ranging from the provision of ingredients, including hemp and CBD, to the co-manufacture and distribution of their finished products. Marketers should ensure that these third-parties adhere to pre-established and agreed upon standards and specifications and provide warranties regarding the safety and efficacy of their products and services. Also, where possible, marketers should consider including provisions in their agreements with these third-parties that would require them to provide indemnification in the event of actual or claimed losses. Marketers should also insist that their third-party suppliers and service providers maintain sufficient levels of insurance coverage and that they be added as additional insureds on their insurance policies.

Conclusion

Marketers of CBD products face near limitless opportunities and a wealth of challenges. While consumer demand remains extraordinarily high, FDA has not yet provided legal pathways for the sale of CBD-containing products, and states’ laws governing CBD are constantly evolving. Lurking in the background are consumer protection and product liability lawyers waiting to jump on

marketers' missteps. To be sure, these challenges make it impossible to eliminate all risks confronting companies marketing CBD-containing products. Consideration of the foregoing suggestions, however, may serve to mitigate against those risks and aid marketers in fulfilling all of the opportunities available to them.

DISCLAIMER: Marijuana is still classified as a Schedule I controlled substance by the U.S. Drug Enforcement Agency, and as such it remains a federal crime to grow, sell and/or use marijuana. Any content contained herein is not intended to provide legal advice to assist with violation of any state or federal law.