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New Wave of Warning Letters Indicates That The FDA Is Looking Beyond Ingestibles And Outrageous Health Claims When It Comes To Selling CBD Products

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Client Advisory

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Introduction

In November 2019, the US Food and Drug Administration released fifteen warning letters (November Warning Letters) to CBD companies for violating the Federal Food Drug and Cosmetic Act (FD&C Act) by, among other things, selling unapproved new drugs. The actions constituting such violations ranged widely from marketing CBD products as treatments for serious diseases to describing cosmetic type CBD products as having anti-inflammatory properties. Prior to the release of the November Warning Letters, avoiding outlandish health claims and not introducing CBD into food products appeared to be a road map for avoiding FDA attention.[1] The FDA's decisions in the November Warning Letters to classify a wide variety of CBD products as unapproved drugs indicates that such road map may no longer work, leaving CBD companies at risk of drawing the attention of the FDA and being identified as violating the FD&C Act by the FDA.

Background

Companies in the CBD industry have been operating in a state of regulatory uncertainty since hemp and its derivatives, including CBD, were removed as a controlled substance under the CSA by the passage of the 2018 Farm Bill. Though the bill relieved producers from much of their concerns relating the CSA[2], in its letter following the passage of the 2018 Farm Bill, the FDA made clear that its authority regarding CBD food products and CBD medical applications remains under the bill.[3] The FDA also made clear that the 2018 Farm Bill is not an invitation to pedal CBD as a cure-all.[4] In its early public announcements, the FDA consistently maintained that making unsubstantiated health claims, as well as adding CBD to food and beverages, violated the FDC&A. In line with the announcements, and until the release of the November Warning Letters, the FDA's warning letters to CBD companies focused almost exclusively on their making of overt health claims relating to CBD and introducing CBD into the human food supply.[5] As a result, prior to the release of the November Warning Letters, CBD companies that did not make egregious health claims or introduce CBD into the human food supply operated with an understanding that, despite potentially running afoul of the FDA's interpretation of the FD&C Act, they would likely fly under the FDA's radar. The FDA's November Warning Letters challenge that understanding.

The FDA's November Warning Letters Indicate the FDA May be Expanding the Scope of What it Finds Objectionable

The November Warning Letters do not break new ground regarding the FDA's interpretation of the FD&C Act. The FDA has always maintained that CBD cannot be sold as a drug or introduced into human or animal food supply until its rulemaking regarding the marketing and sale of CBD is completed. Also in line with previous FDA correspondence, the November Warning Letters focus on companies that are blatantly

violating the FD&C Act by making claims that CBD can fight cancer cells, aid in the treatment of Parkinson's and assist those suffering from multiple sclerosis. But the November Warning Letters go further. The letters identify relatively benign CBD-related claims as evidence that the sale of topical, and seemingly cosmetic, CBD products violate the FD&C Act. The decision by the FDA to identify these products in the November Warning Letters marks a departure by the FDA from its seemingly singular focus on clear violations of the FD&C Act by CBD companies.

The FD&C Act requires all new drugs to be approved by the FDA prior to being introduced into interstate commerce. Under the FD&C Act, a product is classified as a drug if it is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, and/or intended to affect the structure or any function on the body. Both consumable products and topical products may be classified as a drug. The November Warning Letters indicate the FDA examined the websites, social media accounts, and marketing materials of CBD companies to determine if a product was being sold as a drug and therefore violates the FD&C Act.

In the November Warning letters, the FDA cited claims that vary from clear, explicit statements of CBD's efficacy related to fighting serious illness, to the inclusion of certain words in the title of a product, as evidence that products were being sold as drugs in violation of the FD&C Act. The FDA also cited certain claims related to products that on their face appear cosmetic in nature. For example, a "CBD-Infused Sheet Mask" produced by CDRL Nutritional, Inc. was labeled as a drug by the FDA because it was marketed as "anti-inflammatory."[6] Organix Industries, Inc. was cited for its "Maraki Pain Salve." The FDA identified the word "pain" in the name of the product as evidence the product was being marketed as a drug.[7] Other products identified by the FDA as drugs include "CBD Soap," "CBD Hemp Lotion," and "CBD Daytime Moisturizer." Warning letters from the FDA in 2017 and 2018 mirrored the November Warning Letters in identifying CBD products being sold as new drugs in violation of the FD&C Act. Unlike the November Warning Letters, the earlier warning letters only identified claims clearly medical in nature.

Additional Takeaways from the November Warning Letters

In the November Warning Letters, the FDA reiterated its position that CBD, unlike hulled hemp seeds, hemp seed protein, and hemp seed oil, may not be added to human or animal food products. However, unlike the 2017 and 2018 warning letters, the November Warning Letters went further by identifying the sale of CBD pet products as violating the FD&C Act.

Similarly important, the FDA is looking beyond companies' "official" marketing channels, labels, websites etc., to their social media platforms, when determining if products are being marketed and sold as drugs. This means that companies risk attention from the FDA for claims that may not be on product labels or in official marketing brochures, but are instead found in the material put out by overzealous social media managers. As a result, CBD companies should pay close attention to their advertising and social media presence. The use of certain words that may inadvertently convey a medical claim should be avoided, such as inflammation, pain, and rejuvenating, and sufficient oversight should be given to social media managers by senior executives.

The November Warning Letters also indicate that the FDA will review the entire product portfolio of CBD-companies and not focus solely on the sale of products that most clearly violate the FD&C Act. As a result, CBD companies may not be able to simply adjust their CBD Offerings in order avoid the FDA's attention.

Conclusion

The November Warning Letters appear to represent the FDA's step towards enforcing the rules surrounding CBD, rather than simply stating them. The November Warning Letters are not ground breaking, and with respect to the FDA's interpretations of the FD&C Act, are consistent with prior letters. But CBD companies operate in reality, not theory, and as a practical matter, the FDA's issuance of the November Warning Letters means that CBD companies that may have previously flown under the radar while technically operating in violation of the FD&C Act may

no longer be able to do so. By identifying seemingly minor product claims as grounds for violation of the FD&C Act, the FDA has left CBD companies in a minefield whether they may inadvertently find themselves running afoul of the FD&C Act.

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[1] Following this road map did not result in compliance with the FD&C Act, as a practical matter, it generally avoided drawing the FDA's attention.

[2] CBD companies still need to ensure their products do not contain greater that 0.3% THC on a dry weight basis to avoid violation of the CSA.

[3] https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys.

[4] https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation.

[5] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/rooted-apothecary-llc-585312-10102019.

[6] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cdrl-nutritional-inc-593398-11222019.

[7] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/organix-industries-inc-dba-plant-organix-593512-11222019.

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