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FDA Issues Warning Letter to Curaleaf Over CBD Claims - *NJ Cannabis Blog*

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On July 22, 2019, the FDA issued a warning letter to Curaleaf, Inc. relating to statements on its website relating to claims about its CBD products. The FDA warned that four of its products (CBD lotion, pain-relief patch, tincture and disposable vape pen) are unapproved new drugs and misbranded drugs.

Despite the growing popularity of CBD products, the FDA has issued previous warning letters and made clear that it will enforce the Federal Food, Drug & Cosmetics Act (FD&C), especially when merchants make claims about the health benefits of CBD.

The FDA issued this warning because Curaleaf's website and social media posts, according to the FDA, show an intent that the products be used as drugs based on statements that the products could be used "for chronic pain"; that CBD is an "all-natural source of relief used to address the symptoms of many common conditions, such as chronic pain, anxiety, … ADHD"; "CBD is known for its anti-anxiety properties that can promote relaxation and stress relief". The FDA also cited Curaleaf for advertising that research has shown CBD is "effective in treating Parkinson's disease"; "has been shown to be linked to the effective treatment of Alzheimer's disease"; "CBD can in fact reduce the severity of opioid-related withdrawal"; "effective in killing human breast cancer cells"; "Some of the most researched and well-supported hemp oil uses include… Anxiety, depression, post-traumatic stress disorders, and even schizophrenia…Chronic pain from fibromyalgia, slipped spinal discs… Eating disorders and addiction."

As the warning letter explains, CBD products are not generally recognized as safe and effective by the FDA for those uses and therefore constitute "new drugs" under the FD&C. "New drugs" require FDA approval before they can be sold in interstate commerce.

The FDA further cited Curaleaf for "misbranding" their products because they fail to provide adequate directions for use as required by the FD&C. Because these are new drugs that have not been approved and because the conditions are not amenable to self-diagnosis by non-medical practitioners, the FDA warned that it is not possible to provide adequate directions for use.

The FDA further took issue with Curaleaf referring to some of its CBD products as dietary supplements. The FDA's letter repeats its position that because CBD is an active ingredient in an approved drug (Epidiolex), that it cannot also be a dietary supplement (unless it was marketed as a dietary supplement prior to its approval in a drug).

Not to be left out, the FDA also warned Curaleaf that its CBD for pets product, for similar reasons, was a "new animal drug" that has not been approved by the FDA.

While the FDA sent this letter to Curaleaf, a high profile producer of CBD products, it is likely intended as a warning to other purveyors of CBD products to review their claims about the uses of CBD.