

FDA a Buzzkill for 15 CBD Companies

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On November 25, 2019, the Food and Drug Administration sent a wave of warning letters to fifteen CBD companies claiming they are breaking federal food, drug, and cosmetic laws based on their current CBD product marketing and labelling. Prior to this, the FDA had separately sent letters to seven other CBD companies in 2019 and to only one CBD company in 2018. A comprehensive list of CBD-related warning letters sent by the FDA can be found [here](#). The FDA accompanies the most recent letters with a [press release](#) and a revised [Consumer Update](#) discussing the FDA's potential concerns about CBD.

As in the past, these letters targeted companies marketing CBD products to treat diseases or claiming that CBD has therapeutic uses for humans and/or animals. The letters also target companies that market CBD products as dietary supplements or as an additive to human and animal foods. At their most basic, the FDA's objections are rooted

in the agency's interpretation of the Food, Drug, and Cosmetic Act ("FDCA"), which the FDA claims precludes CBD from being classified as a dietary supplement because CBD is also an active ingredient in the drug Epidiolex. The FDA also takes the position that, under the FDCA, CBD products could be viewed as new, unproven drugs where a company promotes use of CBD for curing and treating diseases and ailments.

Despite the FDA's fairly aggressive position and action in issuing the warning letters, the FDA's press release indicates that it continues to "explore potential pathways for various types of CBD products to be lawfully marketed." The FDA plans to provide an update on its progress regarding the agency's approach to these products "in the coming weeks." As of the time of writing this post, the FDA has not issued a further update. However, these statements still show signs of a potential reversal or at least softening of the FDA's treatment of CBD.

So, what lessons can CBD companies learn from these letters in hopes of avoiding the ire of the FDA? First, just because a company did not receive a letter from the FDA, that does not necessarily mean it is in compliance with the FDA's current interpretation of the FDCA or that it won't receive a letter in the future. The FDA has a limited enforcement budget and appears to continue to target offenders making extreme performance claims about CBD. Second, making statements about perceived health/wellness benefits of CBD products is a major no-no. And this doesn't just apply to obviously extreme claims, such as stating that CBD may cure cancer. It also applies to less extreme statements about CBD performance, such as claiming that CBD products help with "skin rejuvenation" or "joint & muscle relief" or referring to CBD products as "dietary supplements" or food. Companies would be well served by implementing multi-level review processes (including external review where feasible) to ensure marketing materials, packaging, and websites do not fall on the wrong side of this line, at least until the FDA issues further and more specific guidance.

Dorsey will continue to monitor the FDA's actions and updates in this area.