New DEA Rule May Threaten CBD Manufacturing

A new rule from the U.S. Drug Enforcement Agency (DEA) has caused considerable concern within the cannabidiol (CBD) industry. The rule relates to the distinction made in the 2018 Farm Bill that removed certain cannabis products, such as industrial hemp and those containing hemp-derived CBD, with levels of THC not exceeding 0.3% by weight from the federal controlled substances list. THC is the psychoactive substances most associated with a marijuana "high." DEA's interim final rule appears straightforward at first glance: cannabis products containing more than 0.3% by weight are subject to DEA enforcement as controlled substances. The rule appears to mean, however, that THC levels can never exceed 0.3% at any point during the product's manufacturing process, even if the final product offered for sale had THC at appropriate levels. The Interim Final Rule's Requirements The DEA's new rule notes that cannabis products cannot exceed the 0.3% THC limit if they are to meet the 2018 Farm Bill's definition of "hemp," and thus qualify for the exemption from the controlled substances list. The agency has stated: "[A] cannabis derivative, extract, or product that exceeds the 0.3% [THC] limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less [THC] on a dry weight basis." The DEA has also noted the findings of its sister federal agency the U.S. Food and Drug Administration (FDA), which has reported that many CBD products were found to not contain the levels of CBD claimed on product labeling. The Implications As CBD manufacturers know, the manufacturing process may see the THC levels in an unfinished product exceed the 0.3% THC, even if the final product offered for public sale meets the threshold. The DEA's interim final rule creates the possibility that the product, not yet offered for sale, might nonetheless be a "controlled substance" if it exceeds the 0.3% THC level. Such an interpretation would obviously be highly problematic for CBD product manufacturers. What's Next The DEA's interim final rule is effective as of August 21, 2020. However, the public may provide comments to the agency here, and commenters should be sure to reference the DEA Docket Number "RIN 1117- AB53/ Docket No. DEA-500" on all submissions. Comments are permitted until 11:59 PM Eastern Time on October 20, 2020. As of August 26, 2020, the agency has already received over 1,000 comments.

Authors



Barak Cohen

Partner
BCohen@perkinscoie.com 202.654.6337

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