DEA REPORTEDLY SET TO ISSUE NEW SYNTHETIC CANNABINOIDS, INCLUDING NEW RULES FOR DELTA-8 THC

May 31, 2023

By: Cannabis Law Team Leader Richard Blau

The wheels of the federal government tend to turn slowly. That said, the Drug Enforcement Administration (DEA) reportedly will soon propose new administrative regulations to clarify that synthetically manufactured cannabinoids like delta-8 tetrahydrocannabinol (THC) are prohibited controlled substances within the scope of the Controlled Substances Act of 1970 (CSA).

The CSA classifies THC as a controlled substance in Schedule I of the CSA.[1] Federal law currently defines THC as substances "*naturally contained in a plant of the genus Cannabis, as well as synthetic equivalents of the substances contained in the cannabis plant and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant.*"[2]

Previously, the DEA has suffered mixed results in its attempts to declare certain cannabis derivatives as Schedule 1 narcotics. For example, in February of 2023, the DEA stated that delta-8 THC acetate ester (delta-8 THCO) and delta-9 acetate ester (delta-9 THCO) are not hemp but Schedule I controlled substances under the CSA. The DEA decided these substances could not be deemed lawful hemp-derived products because they do not naturally occur in hemp.

According to the DEA:

> Whether a cannabinoid product that has been synthetically produced from non-cannabis materials is controlled depends on whether the product contains "any quantity" of a synthetically produced tetrahydrocannabinol. *See* 21 U.S.C. 812, Schedule 1(c)(17); 21 C.F.R. 1308.11(d)(31); *see also* Implementation of the Agriculture Improvement Act of 2018, 85 FR 51639, 51641 (2020).

[1] *See* 21 U.S.C. §812, Schedule I(c)(17).
[2] 21 C.F.R. 1308.11(d)(31).

> This includes cannabinoid products that are chemically identical to cannabinoids that naturally occur in the cannabis plant but that have been manufactured synthetically rather than procured by extraction from the plant."[3]

However, the DEA's conclusion appears to be in tension with the statutory definition of hemp[4] and the U.S. Court of Appeals for the Ninth Circuit's opinion in *AK Futures LLC. v. Boyd St. Distro, LLC.*[5], which predicates a substance's status under law to its source, rather than to whether it is synthetic or naturally occurring. In that case, the Ninth Circuit ruled that the Agricultural Improvement Act's definition of "hemp," in the provision removing "hemp" from the CSA's definition of "marihuana," unambiguously precluded a distinction based on manufacturing method. According to the federal appellate court, the 2018 Farm Act broadly defined "hemp" and did not limit its application according to manner by which "derivatives, extracts, and cannabinoids" were produced, but rather, expressly applied to "all" such downstream products so long as they did not cross 0.3% delta-9 THC threshold.[6]

Although companies generally should operate in compliance with the DEA's guidance, the existence of doubt regarding the DEA's earlier conclusion likely contributed to the agency's determination to issue the new proposed regulations regarding synthetically manufactured cannabinoids.

At the agency's **2023 DEA Supply Chain Conference** held earlier this month, Terrance Boos, the Section Chief of DEA's Drug and Chemical Evaluation Section, said that officials have received "multiple petitions" regarding the regulation of synthetic cannabis products like delta-8 THC that fall outside the current legal definition of "marihuana." Those inquiries sought agency clarification regarding the legal status of cannabis components other than delta-9 THC, including:

- Cannabidiol (CBD);
- Delta-8 Tetrahydrocannabinol **(**Delta-8 THC, Δ^8-THC);
- Tetrahydrocannabinolic acid (THCA);
- Tetrahydrocannabivarin (THCV);
- Cannabinol (CBN);
- Cannabigerol (CBG);
- Cannabichromene (CBC);
- Delta-10-Tetrahydrocannabinol (Delta-10-THC, Δ^{10}-THC, alternatively numbered as Δ^2-THC);
- Delta-8-tetrahydrocannabinol acetate ester (delta-8-THC); and
- Delta-9-tetrahydrocannabinol acetate ester (Delta-9 THCO).

As a result of those inquiries, DEA is modifying its regulations regarding cannabis constituents based on recommendations from the U.S. Department of Health and Human Services (HHS).

The DEA no longer regulates naturally-produced hemp-derived cannabidiol as long as the preparations containing CBD have no more than 0.3 percent THC by dry weight. Based on a slideshow **presentation** from the 2023 DEA Supply Chain Conference, it appears the agency may be considering a plan to de-schedule synthetic CBD. DEA Section Chief Boos told the conference attendees

---

[3] Drug Enforcement Administration, "Drug & Chemical Evaluation Section Power Point Presentation (May 4, 2023) at slide 29; this Power Point presentation is accessible online at: https://www.deadiversion.usdoj.gov/mtgs/supply_chain/conf_2023/Boos.pdf.

[4] The Agriculture Improvement Act of 2018, Pub. L. No. 115-334 (2018) (commonly known as the "2018 Farm Bill") defined hemp to include all "derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers" with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. 21 U.S.C. § 802(16)(B)(i). Hemp is excluded from the definition of "marihuana" and Schedule I under the CSA. 21 C.F.R. § 1308.11(d)(31)(ii). Tetrahydrocannabinols (THC), including those "naturally contained" in the cannabis plant as well as their "synthetic equivalents," remain controlled Schedule I substances. 21 U.S.C. § 812; 21 C.F.R. 1308.11(d)(31).

[5] 35 F.4th 682 (9th Cir. 2022).

[6] Id. at 693.

that the forthcoming rulemaking intends to clarify the legal status of various cannabinoids since hemp and its derivatives were federally legalized under the 2018 Farm Bill.

According to top cannabis researcher Brightfield Group, the CBD market is estimated to grow from $4.4 billion in annual sales through 2022 to more than $10.3 billion in annual sales by 2028 if federal regulation provides much-needed clarity. According to the Brightfield Group, federal regulation could allow CBD products to be sold as dietary supplements and food additives, accelerating the growth of ingestible products such as beverages and edibles. Federal regulation also likely would increase the acceptance and distribution of CBD products among mainstream retailers.

The cannabis industry would much appreciate some clarity. Whether that clarity is forthcoming, however, remains to be seen.

Richard M. Blau leads the GrayRobinson Cannabis Law Team, focusing on the laws and regulations that govern the cultivation and production, processing, distribution, sale, and dispensing of medical marijuana, hemp, Cannabidiol (CBD), and related cannabis products. Richard has been rated by Chambers USA since 2007, was among the first lawyers in America to be rated Band 1 Nationwide for Cannabis Law, and is listed in Best Lawyers® in America. Richard has been involved extensively with the legalization of cannabis in Florida since its outset, with the passage of the Compassionate Medical Cannabis Act of 2014 (SB 1030) into law on June 6, 2014. Richard also has represented several investors in the cannabis industry, advising principals on compliance issues associated with Florida Medical Marijuana Treatment Center (MMTC) license acquisitions.