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Case 4

U.S. Department of Justice Drug Enforcement Administration 8701 Morrissette Drive Springfield, Virginia 22152

www.dea.gov

September 15, 2021

Donna C. Yeatman, R.Ph. Executive Secretary Alabama Board of Pharmacy 111 Village Street Birmingham, Alabama 35242



Dear Dr. Yeatman:

This is in response to your letter dated August 19, 2021, in which you request the control status of delta-8-tetrahydrocannabinol (Δ^8 -THC) under the Controlled Substances Act (CSA). The Drug Enforcement Administration (DEA) reviewed the CSA and its implementing regulations with regard to the control status of this substance.

 Δ^8 -THC is a tetrahydrocannabinol substance contained in the plant *Cannabis sativa L*. and also can be produced synthetically from non-cannabis materials. The CSA classifies tetrahydrocannabinols as controlled in schedule I. 21 U.S.C. 812, Schedule I(c)(17); 21 CFR § 1308.11(d)(31). Subject to limited exceptions, for the purposes of the CSA, the term "tetrahydrocannabinols" means those "naturally contained in a plant of the genus Cannabis (cannabis plant), 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." 21 CFR § 1308.11(d)(31). Thus, Δ^8 -THC synthetically produced from non-cannabis materials is controlled under the CSA as a "tetrahydrocannabinol."

The CSA, however, excludes from control "tetrahydrocannabinols in hemp (as defined under section 16390 of Title 7)." Hemp, in turn, is defined as "the plant *Cannabis sativa L*. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol $[(\Delta^9\text{-THC})]$ concentration of not more than 0.3 percent on a dry weight basis." 7 U.S.C. 16390(1).

Accordingly, cannabinoids extracted from the cannabis plant that have a Δ^9 -THC concentration of not more than 0.3 percent on a dry weight basis meet the definition of "hemp" and thus are not controlled under the CSA. Conversely, naturally derived cannabinoids having a Δ^9 -THC concentration more than 0.3 percent on a dry weight basis is controlled in schedule I under the CSA as tetrahydrocannabinols.¹

The Agricultural Improvement Act of 2018 (AIA), Pub. L. 115-334, § 12619, amended the CSA to remove "tetrahydrocannabinols in hemp" from control. See 21 U.S.C. § 812, Schedule I(c)(17). As noted, however, "hemp" is defined to "mean the *plant* Cannabis sativa L. and *any part of that plant*, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." 7 U.S.C. 16390 (emphasis added). Thus, only tetrahydrocannabinol in or derived from the cannabis plant—not synthetic tetrahydrocannabinol—is subject to being excluded from control as a "tetrahydrocannabinol[] in hemp."

Donna C. Yeatman, R.Ph

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If you have any further questions, please contact the Drug and Chemical Evaluation Section at DPE@usdoj.gov or (571) 362-3249.

Sincerely,

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Terrence L. Boos, Ph.D., Chief Drug & Chemical Evaluation Section Diversion Control Division

cc: Birmingham Office