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June 17, 2021

Hon. Joe Bilby
General Counsel
Kentucky Department of Agriculture
105 Corporate Drive
Frankfort, KY 40601
By Email only: Joe.Bilby@ky.gov

Re: Kentucky Hemp Association
Delta-8-tetrahydrocannabinol

Dear Mr. Bilby:

I have been retained to represent the Kentucky Hemp Association (and others) in connection with your letter dated April 19, 2021 (“Guidance”). That Guidance has taken on new importance in the last couple weeks, as the Kentucky State Police, relying on the Guidance, has undertaken raids associated with delta-8-tetrahydrocannabinol (“Delta-8-THC”) on certain small businesses around the state, and at the same time, my client informs me that the Kentucky Department of Agriculture has undertaken inspections of producers of hemp around the state to enforce the content of your letter related to Delta-8-THC.

For my part, I have thoroughly researched federal law, and have concluded, as a result, that your April 19, 2021 Guidance is in error. First you contend that:

As you know, in 2018 Congress created a narrow exemption from the Controlled Substances Act’s definition of “marijuana” (DEA numbers 7350 and 7360) for hemp that contains not more than 0.3% total Delta-9 THC. Cannabis with total Delta-9 THC in excess of that threshold remains a Schedule I substance.

We mostly agree. Congress defined “hemp” in the 2018 Farm Bill, which is codified at 7 U.S.C. 1639o. And it exempted “hemp” as defined in that section, from the definition of controlled substances in the Controlled Substances Act. 21 USCS § 802(16)(B).¹ Congress did not, however, specifically exempt the DEA control numbers as you indicate in your letter.

¹ That section provides: “(B) The term ‘marihuana’ **does not include**—

(i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946 [7 USCS § 1639o]; or

(ii) the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.” (emphasis added).

Then you contend that:

There is no equivalent exemption for Delta-8 THC. That being the case, the manufacture and marketing of products containing Delta-8 THC, in any quantity or concentration level, remains prohibited by federal law.

In support, you reference the orange book.² But, as it turns out, the actual legal question is a bit more nuanced than a citation to the orange book. The actual regulation for controlled substances – Schedule I – is contained at 21 CFR 1308.11. For tetrahydrocannabinols, which is DEA reference 7370, Schedule I provides at 21 CFR 1308.11(31)(ii) that: “(ii) Tetrahydrocannabinols does not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639o.”³

In turn, 7 U.S.C. 1639o provides a definition for “Hemp,” namely:

(1) Hemp. The term “hemp” means 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.⁴

There is no doubt but that derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers that comes from the *Cannabis sativa* L. plant, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis is within the definition of “Hemp” under both the statute (7 U.S.C. 1639o), and the Schedule I regulation that incorporates the statute (21 CFR 1308.11(31)(ii)). This is so, regardless of the derived concentration of Delta-8-THC.

Because derived products from hemp that do not contain more than 0.3 percent concentration of delta-9 tetrahydrocannabinol are “Hemp” under the 2018 Farm Bill, codified at 7 U.S.C. 1639o, they are not a controlled substance under federal law.

You then conclude in your Guidance:

² https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf (last visited 6/17/2021).

³ For the same reason, the products are not controlled as a “marijuana extract” under 21 CFR 1308.11(58), since regulations define a marijuana extract as “(58) Marihuana Extract 7350 Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus *Cannabis*, containing greater than 0.3% delta-9-tetrahydrocannabinol on a dry weight basis, other than the separated resin (whether crude or purified) obtained from the plant.”

⁴ Kentucky law incorporates this definition of “Hemp.” KRS 260.850(5); KRS 260.8635. It also includes testing for hemp that is limited to delta-9 tetrahydrocannabinol. KRS 250.355; KRS 260.858.

That brings us to state law. Because Delta-8 THC is a Schedule I controlled substance under federal law, it remains a Schedule I controlled substance under state law as well. See 902 KAR 55:015, Section 1(1) (stating that each substance that is scheduled or designated as a Schedule I controlled substance under federal law “shall be scheduled or designated at the state level as a Schedule I controlled substance”).

You are correct that, as a general matter, Kentucky law on controlled substances incorporates federal law. But you are incorrect, as pointed out above, that products containing Delta-8-THC are controlled substances, provided they contain less than 0.3 percent concentration of delta-9 tetrahydrocannabinol on a dry weight basis. Assuming they are below the Delta-9 concentration, as mentioned above, they are “Hemp,” within the federal definition at both 7 U.S.C. 1639o and 21 CFR 1308.11(31)(ii).

As a practical matter, all hemp contains some levels of Delta-8-THC, and, in fact, the USDA has noted as much recently in the rulemaking for domestic production. 86 FR 5596 at 5621 (and rejecting a request to test for Delta-8-THC concentrations to determine compliance).

I have searched in vain, for any DEA or USDA Guidance or other documents related to Delta-8-THC and the points made above (obviously to figure out who the appropriate Defendants might be in any lawsuit). I have found none. If there are any such documents, please send them to me or direct me to them.

I have likewise searched, in vain, for any Kentucky law that would support the Guidance, but again have come up short.

Because it is clear that Delta-8-THC is not prohibited under federal law, provided it is derived from hemp that does not exceed the 0.3% delta-9-tetrahydrocannabinol on a dry weight basis threshold, and is not contained in a product that exceeds the 0.3% delta-9-tetrahydrocannabinol on a dry weight basis, it appears that your Guidance is in error.

But more than that, because the Guidance is being enforced as a substantive matter, it is in contravention of multiple provisions of KRS Chapter 13A (and, as it turns out, is also prohibited under Kentucky law that expressly permits the manufacture of hemp, under both the federal and state definitions that are identical).

I am therefore asking you to rescind the Guidance and re-issue guidance consistent with federal and state law. Failing that, I am prepared to bring an appropriate lawsuit for declaratory and injunctive relief against Commissioner Quarles, and others, on behalf of the Kentucky Hemp Association and certain of its members. Please let me know immediately, and by not later than 2:00 p.m. on June 21, 2021, if you will rescind the Guidance and re-issue appropriate guidance. I will bring suit otherwise.

On a final note, if there is some federal guidance document or directive that you believe is contrary to my analysis above (beyond the orange book), which the Commissioner is enforcing, please let me know immediately, so that I can prepare to sue the federal government instead of the Commissioner. I would find that to be somewhat hard to believe, since West

Virginia is actually issuing certificates for products that contained Delta-8, but are below the Delta-9 threshold, but I suppose anything is possible.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Wiest", written in a cursive style.

Christopher Wiest