

kightlaw

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BioWellnessX, Inc.
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Re: Legal Status of Hemp Products, Including THCa Hemp Cannabis Flower and Prerolls, Hemp Derived Delta-9 THC Beverages, and Hemp Derived Delta-9 THC Edibles

This letter is written for BioWellnessX, Inc. (BioWellnessX) regarding the legal status of certain hemp products, including inhalable hemp “cannabis” flower and prerolls, hemp beverages, and hemp edibles. The specific question addressed in this letter is: **“Are hemp products, including harvested hemp flowers and buds, hemp derived beverages, and hemp derived edibles, controlled substances under federal law or the laws of North Carolina when their delta-9 tetrahydrocannabinol (delta-9 THC) concentrations do not exceed 0.3% by dry weight, even if they contain THCa concentrations in excess of 0.3%?”** As discussed in this letter, the answer to this question is **“No”**. With respect to harvested cannabis material and its downstream products, the sole factor that distinguishes between lawful hemp and unlawful marijuana is the concentration of delta-9 THC.

The analysis and conclusions contained in this letter are based on the Agricultural Act of 2014 (2014 Farm Act)¹, the Agricultural Improvement Act of 2018 (Farm Bill)², the federal Controlled Substances Act (CSA)³, the Drug Enforcement Administration’s (DEA) Interim Final Rule (IFR)⁴, the DEA’s letter to the Alabama Board of Pharmacy (Letter)⁵, a DEA letter regarding cannabis seeds and other cannabis materials⁶, a letter to a currently undisclosed recipient in response to a request for the control status of several compounds, including delta-9 THCA⁷, and an opinion by the Ninth

¹ <https://www.govinfo.gov/content/pkg/BILLS-113hr2642enr/pdf/BILLS-113hr2642enr.pdf>

² <https://www.congress.gov/115/bills/hr2/BILLS-115hr2enr.pdf>

³ 21 U.S. Code § 801 *et seq.*

⁴ https://www.deadiversion.usdoj.gov/fed_regs/rules/2020/fr0821.htm

⁵ <https://docs.google.com/viewerng/viewer?url=https://cannabusiness.law/wp-content/uploads/DEA-letter-re-D8-to-Alabama.pdf&hl>

⁶ <https://s3.documentcloud.org/documents/21580238/21-7692-shane-pennington-cannabis-seeds-tissue-genetic-material-11-18-21-signed-1.pdf>

⁷ <file:///Users/rodkight/Downloads/DEA-THCA-and-HHC-letter.pdf>

Circuit Court of Appeals and the district court for the Eastern District of Arkansas⁸. Additionally, this letter discusses the statutes and regulations of North Carolina as they pertain to hemp. This letter does not address any requirements under the federal Food, Drug & Cosmetic Act and associated regulations by the Food and Drug Administration (FDA).

This letter is solely for BioWellnessX, but I have been informed it may be shared with select parties. All third parties are specifically advised that this letter is not intended to be legal advice for any party other than BioWellnessX and should not be construed or relied upon as such. It is accurate as of the date above.

EXECUTIVE SUMMARY

The word “cannabis” is a botanical term referring to the plant *Cannabis Sativa* L. It is not a legal term of art under federal law or the laws of North Carolina. Under both federal law and North Carolina law, the legal terms of art related to cannabis are “hemp”, which is lawful cannabis, and “marijuana”, which is unlawful cannabis. The sole legal difference between legal harvested hemp and illegal marijuana is the concentration of delta-9 THC. Cannabis containing no more than 0.3% delta-9 THC is lawful “hemp”. Cannabis containing more than 0.3% delta-9 THC is unlawful “marijuana”. This distinction flows through to hemp products, which themselves are not controlled substances if their concentrations of delta-9 THC do not exceed 0.3%. The form that a hemp product takes does not change its legal status. For example, a hemp “THCa preroll” joint is just as lawful as a topical hemp CBD cream.

PART 1- DISCUSSION OF THE ISSUE: THE CONCENTRATION OF DELTA-9, NOT THCA, IS THE SOLE FACTOR IN DETERMINING A CANNABIS PRODUCT’S CONTROLLED STATUS

There are dozens of forms of the tetrahydrocannabinol (THC) molecule. Some of these forms are called isomers. An isomer is one of two or more compounds that contain the same number of atoms of the same elements but differ in structural arrangement and properties.⁹ There are at least thirty THC isomers¹⁰, of which delta-9 THC is the most well-known. Additionally, delta-8 THC (D8-THC) and delta-10 THC (D10-THC) have recently gained more attention in the media and marketplace. As discussed below, the only THC isomer that is used to determine whether harvested hemp and hemp products are lawful under federal law is delta-9 THC. The quantity and concentration of other THC isomers, and other cannabinoids and forms of THC, including THCa, are totally irrelevant with respect to the legal status of harvested hemp and hemp products.¹¹

⁸ *AK Futures LLC v. Boyd St. Distro, LLC*, 8:21-cv-01027-JVS-ADS (C.D. Cal. Jun. 15, 2022), *Bio Gen LLC et al v. Sanders et al*, 4:23 CV 718 BRW (September 7, 2023) [Document 65]

⁹ <https://www.merriam-webster.com/dictionary/isomer>

¹⁰ See, eg, this website: <https://cannabislifenetwork.com/amount-of-isomers-in-thc/>. See also, this website: <https://cannabusiness.law/thc-analogs-a-family-divided/>

¹¹ Note that, while the concentration of THCa is not relevant in determining the legal status of harvested hemp or hemp products, it is relevant in determining the legal status of hemp that has not been harvested. This is because USDA regulations require hemp to be tested for delta-9 THC using a “post-

PART 2- HEMP IS NOT A CONTROLLED SUBSTANCE

Hemp initially became exempt from the CSA, and thus removed from the list of controlled substances, by virtue of the 2014 Farm Act when produced pursuant to a state's industrial hemp pilot program. The current Farm Bill, enacted at the end of 2018, removed both "hemp" and "THC in hemp" from the CSA.¹² Hemp is lawful throughout the United States (US).

The Farm Bill defines "hemp" expansively. The definition includes the hemp plant 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 THC concentration of not more than 0.3 percent on a dry weight basis."¹³ (*emphasis added*)

The word "cannabis" is botanical term. It is not a term of art and has no legal meaning. Under federal law the terms of art related to cannabis are "hemp" and "marijuana". The sole distinction between lawful cannabis (hemp) and unlawful cannabis (marijuana) is the concentrations of delta-9 THC in the harvested material. Harvested cannabis with delta-9 THC concentrations that do not exceed 0.3% is legal hemp. On the other hand, harvested cannabis with delta-9 THC concentrations that exceed 0.3% is illegal marijuana. The concentrations of the other cannabinoids in harvested cannabis, including THCa, are irrelevant with respect to its legal status.¹⁴ If the delta-9 THC concentration in harvested hemp or a hemp product does not exceed 0.3% by dry weight, then it is not a controlled substance under federal law.

It is important to note that the controlled status of a compound does not depend on its method of use or ingestion. If a substance is controlled, then it is controlled regardless of its intended method of use. For instance, cocaine remains a schedule 2 controlled substance regardless of whether it is used as a powder, "rock", or intravenous liquid. Similarly, if a substance is not controlled, then its intended method of use cannot and does not make it controlled. Hemp and its cannabinoids, extracts, derivatives, etc. are not controlled substances and neither the specific type of hemp product nor the various methods of ingesting or using them changes this fact. Hemp is not a controlled substance regardless of the type of product in which it is used or the way it is used. A THCa cannabis hemp preroll joint is just as lawful as a topical hemp CBD cream. BioWellnessX's product lines, consisting of THCa hemp cannabis flower and prerolls, hemp derived delta-9 THC

decarboxylation method" before it can be harvested. Because THCa converts to delta-9 THC when decarboxylated the THCa concentration of a pre-harvest hemp sample matters. However, and as discussed in this letter, this only applies to hemp that has not been harvested. It does not apply to harvested hemp and products made from it. Further reading on this issue, including testing standards, can be found at the following websites: <https://cannabusiness.law/total-thc-and-harvested-hemp/>, <https://cannabusiness.law/thca-and-the-dea-rod-breaks-down-the-latest-news/>

¹² 21 U.S.C. § 802(16)(B): "The term "marihuana" does not include— (i) hemp, as defined in section 1639o of title 7."

¹³ 7 U.S.C. § 1639o(1)

¹⁴ <https://cannabusiness.law/thca-and-the-dea-rod-breaks-down-the-latest-news/>

beverages, and hemp derived delta-9 THC edibles all share the same legal status: they are lawful under federal law and the laws of North Carolina because their delta-9 THC concentrations do not exceed 0.3% by dry weight.

IT IS LAWFUL TO TRANSPORT HEMP AND HEMP-DERIVED PRODUCTS IN INTERSTATE COMMERCE

The interstate transfer of hemp is authorized by 7 USC § 1621 subsection 10114(b), which states in relevant part: “*No State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products produced in accordance with subtitle G of the Agricultural Marketing Act of 1946 (AMA) (as added by section 10113) through the State or the territory of the Indian Tribe, as applicable.*”¹⁵ Although state laws vary with respect to hemp and hemp products, it is absolutely clear that states and Indian tribes may not prohibit the transport of them through their borders. Some of BioWellnessX’s hemp products come from other states. The fact that they are shipped across state lines does not change their lawful status.

HEMP AND HEMP PRODUCTS ARE LAWFUL ACCORDING TO THE DEA

I. The Interim Final Rule

The DEA has expressly stated that hemp and hemp products are not controlled substances. On August 21, 2020, the DEA published its Interim Final Rule (IFR) in the federal register¹⁶. In its IFR, the DEA stated:

*“In order to meet the definition of “hemp”, and thus qualify for the exemption from [S]chedule I, the derivative must not exceed the 0.3% delta-9 THC limit. The definition of “marihuana” continues to state that “all parts of the plant *Cannabis sativa* L.” and “every compound manufacture, salt, derivative, mixture, or preparation of such plant,” are [S]chedule I controlled substances unless they meet the definition of “hemp” (by falling below the 0.3% delta-9 THC limit on a dry weight basis)...” (Emphasis added).¹⁷*

The DEA’s IFR continues by stating that the listing for “tetrahydrocannabinols” (ie, “THC”) under 21 U.S.C. 812(c) “*does not include tetrahydrocannabinols in hemp.*”

The DEA’s IFR confirms that hemp products, which by definition must contain no more than 0.3% delta-9 THC on a dry weight basis, are not controlled substances in the US.

II. DEA Public Statements

¹⁵ <https://uscode.house.gov/statviewer.htm?volume=132&page=4914#>

¹⁶ “*Implementation of the Agriculture Improvement Act of 2018*”, Federal Register Volume 85, Number 163 (Friday, August 21, 2020).

¹⁷ <https://www.govinfo.gov/content/pkg/FR-2020-08-21/html/2020-17356.htm>

In addition to the IFR, the DEA has indicated in four public statements that cannabinoids and other cannabis materials are not controlled substances when their delta-9 THC concentrations do not exceed 0.3% on a dry weight basis.

1. DEA's First Public Statement- Town Hall Meeting

The DEA's first public statement is in the form of a video webinar called a "Town Hall with USDA and DEA" conducted by the Florida Department of Agriculture and Consumer Services (FLDACS) on June 24, 2021. In the Town Hall webinar, the DEA representative stated the following:

"[W]hat I want to say, and I'll be very, very deliberate and clear. At this time, I repeat again, at this time, per the Farm Bill, the only thing that is a controlled substance is delta-9 THC greater than 0.3% on a dry-weight basis." (emphasis added)¹⁸

2. DEA's Second Public Statement- Letter to the Alabama Board of Pharmacy

The DEA publicly addressed the legal status of the various forms of THC in hemp again in the form of a response letter to the Alabama Board of Pharmacy (ABOP) dated September 15, 2021.¹⁹ In this letter, Terrence L. Boos, Ph.D., Chief of the DEA's Drug and Chemical Evaluation Section of the Diversion Control Division, responds to the ABOP's request for the controlled status of delta-8 THC. After differentiating between the legal status of marijuana and hemp, both of which are botanically "cannabis sativa L", the DEA states:

"[C]annabinoids extracted from the cannabis plant that have a delta-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."

Additionally, the DEA states the following in a footnote:

"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. 1639o. 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." (emphasis added)²⁰

¹⁸ The pertinent portions of the webinar can be viewed at this website: <https://cannabusiness.law/is-d8-from-hemp-a-controlled-substance-dea-says-no/>

¹⁹ <https://albop.com/oodoardu/2021/10/ALBOP-synthetic-delta8-THC-21-7520-signed.pdf>

²⁰ Ibid.

3. DEA's Third Public Statement- Response Letter Regarding Seeds and Cannabis Materials

In response to an inquiry regarding the DEA's interpretation of its implementing regulations regarding cannabis the DEA stated in a letter dated January 6, 2022: “[M]aterial that is derived or extracted from the cannabis plant such as tissue culture and any other genetic material that has a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis meets the definition of “hemp” and thus is not controlled under the CSA.” (emphasis added)²¹

4. DEA's Fourth Public Statement- Response Letter Regarding the Control Status of Several Compounds

On June 9, 2023, the DEA issued a letter to a currently undisclosed recipient in response to a request for the control status of several compounds, including delta-9 THCA.²² In that letter, the DEA states: “[C]annabinoids that are extracted from the cannabis plant and that have a delta-9 THC concentration of not more than 0.3% on a dry weight basis meet the definition of ‘hemp’.” The DEA also addresses the control status of delta-9 THCA, stating:

“In regards to delta-9-THCA, Congress has directed that, when determining whether a substance constitutes hemp, delta-9 THC concentration is to be tested “using post-decarboxylation or other similarly reliable methods.” 7 USC § 1639p(a)(2)(A)(ii); 7 USC § 1639q(a)(2)(B). The “decarboxylation” process converts delta-9 THCA to delta-9 THC. Thus, for the purposes of enforcing the hemp definition, the delta-9 THC level must account for any delta-9-THCA in a substance.... Accordingly, cannabis derived delta-9 THCA does not meet the definition of hemp under the CSA because upon conversion for identification purposes as required by Congress, it is equivalent to delta-9 THC.”²³

In this portion of the letter, the DEA is clearly referring to hemp that has not been harvested. This is because, while federal law requires the use of a post-decarboxylation test prior to harvesting hemp, neither a post-decarboxylation test, nor any test, applies to post-production hemp for the purposes of determining its control status. The two statutes cited by the DEA in its letter are the only two places in the Agriculture Improvement Act of 2018, commonly known as the “2018 Farm Bill”, that the term “post decarboxylation” appears. They both apply solely to hemp production.

In the first statutory provision, 7 USC § 1639p(a)(2)(A)(ii), Congress sets forth the criteria that states and Indian tribes must comply with in order to “*have primary regulatory authority over the production of hemp*” within their jurisdictions. The second statutory provision, 7 USC § 1639q(a)(2)(B), is similar in that it sets forth the criteria that the USDA shall use to “*monitor and*

²¹ <https://s3.documentcloud.org/documents/21580238/21-7692-shane-pennington-cannabis-seeds-tissue-genetic-material-11-18-21-signed-1.pdf>

²² <file:///Users/rodkight/Downloads/DEA-THCA-and-HHC-letter.pdf>

²³ *Ibid.*

regulate [hemp] production” in states that do not have an approved hemp plan and thus do not have primary authority over hemp production within their jurisdictions.

The key word in the above provisions is “production”. In the context of hemp, “production” is a legal term of art. Under 7 CFR § 990.1, to “produce” means: “*To grow hemp plants for market, or for cultivation for market, in the United States.*” Additionally, 7 CFR § 718.2 defines a “producer” as “*an owner, operator, landlord, tenant, or sharecropper, who shares in the risk of producing a crop and who is entitled to share in the crop available for marketing from the farm, or would have shared had the crop been produced. A producer includes a grower of hybrid seed.*” To produce hemp means to grow it.

Since the post-decarboxylation test clearly applies to producers, the DEA is correct with respect to hemp that has not been harvested when it states that “*for the purposes of enforcing the hemp definition, the delta-9 THC level must account for any delta-9-THCA.*” However, once the pre-harvested hemp has accounted for delta-9 THCA and passed the required post-decarboxylation test, it may be harvested and no further tests are required. Further, as discussed above, the DEA has confirmed that, “*the only thing that is a controlled substance is delta-9 THC greater than 0.3% on a dry-weight basis.*”^{24 25}

The DEA’s public statements all clearly indicate that harvested hemp and hemp products containing no more than 0.3% delta-9 THC on a dry weight basis are lawful. This includes THCa hemp cannabis flower and prerolls.

FEDERAL COURTS CONFIRM THAT HEMP PRODUCTS ARE NOT CONTROLLED SUBSTANCES

The federal Court of Appeals for the Ninth Circuit issued an opinion regarding hemp products, specifically products containing delta-8 THC, in the context of a trademark dispute. In its opinion, the Ninth Circuit noted that “*the only statutory metric for distinguishing controlled marijuana from legal hemp is the delta-9 THC concentration level.*” (*emphasis added*)²⁶ Additionally, in a separate case involving hemp, the federal district court for the Eastern District of Arkansas ruled: “*Under the 2018 Farm Bill’s standard, the only way to distinguish controlled marijuana from legal hemp is the delta-9 THC concentration level. Additionally, the definition extends beyond just the plant to all derivatives, extracts, [and] cannabinoids. The definition covers downstream products and substances, if their delta-9 THC concentration does not exceed the statutory threshold.*”²⁷ (*emphasis added*)

²⁴ See footnote 18, above.

²⁵ The following website discusses this issue: <https://cannabusiness.law/thca-and-the-dea-rod-breaks-down-the-latest-news/>

²⁶ *AK Futures LLC v. Boyd St. Distro, LLC*, 35 F.4th 682 (9th Cir. 2022)

²⁷ *Bio Gen LLC et al v. Sanders et al*, 4:23 CV 718 BRW (September 7, 2023) [Document 65]

BioWellnessX’s cannabis products, all of which contain no more than 0.3% delta-9 THC on a dry-weight basis, are not controlled substances under US federal law. They are all lawful “hemp” and conform to the Farm Bill, the CSA, and the IFR. They also comply with the legal metric set forth by the Ninth Circuit Court of Appeals and the district court for the Eastern District of Arkansas.

PART 3- HEMP PRODUCTS ARE NOT CONTROLLED SUBSTANCES IN NORTH CAROLINA

North Carolina (NC) takes an expansive and progressive view of hemp and hemp products. Specifically, neither “hemp” nor “hemp products” are controlled substances in NC when their delta-9 THC concentrations do not exceed 0.3% by dry weight. On June 30, 2022 the NC General Assembly (NCGA) enacted SB 455, called “An Act to Conform the Hemp Laws with Federal Law by Permanently Excluding Hemp from the State Controlled Substances Act”.²⁸ This statute defines “hemp” exactly as it is defined under federal law. Additionally, the statute defines “hemp products” to include “all products made from hemp”. Finally, the statute modifies the definition of “marijuana” in NC Controlled Substances Act by stating: “The term [marijuana] does not mean hemp or hemp products.”

On July 11, 2022 the NCGA enacted HB 252.²⁹ It addresses a number of issues, including hemp. Under HB 252 the definition of “tetrahydrocannabinols” (ie, THC) is modified so that it does not include “THC found in hemp or a product with a delta-9 THC concentration of not more than 0.3% on a dry weight basis.”

Based on these two laws, hemp products which contain delta-9 THC concentrations that are within 0.3% on a dry weight basis are not controlled substances in NC.

CONCLUSION

Harvested cannabis material, including buds and flowers, containing delta-9 THC concentrations that do not exceed 0.3% by dry weight are lawful hemp under federal law, regardless of their concentrations of THCa or any other cannabinoid. As discussed in this letter, this conclusion is supported by all three branches of the federal government: by Congress in the hemp provisions of the Farm Bill, by the Executive in the DEA’s IFR and other public statements, and by the federal courts. Additionally, this conclusion is supported by the laws of North Carolina.

Sincerely,



Rod Kight,
Attorney

²⁸ <https://www.ncleg.gov/Sessions/2021/Bills/Senate/PDF/S455v5.pdf>

²⁹ <https://www.ncleg.gov/Sessions/2021/Bills/House/PDF/H252v6.pdf>