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RE: Concerning the Legality of Cannabidiol (CBD) Oil under Federal & Colorado Law

This law firm represents iPuff Vape LLC. This letter is provided on behalf of iPuff Vape LLC in response to a request for a legal opinion about the federal and state legality of CBD products derived from industrial or agricultural hemp. Based upon my legal research and analysis, my professional opinion is that the following detailed analysis applies to the sale of CBD products in Colorado. Please note that this letter can not guaranty a potential outcome in a court of law, but is a comprehensive review of the current state of the law in the federal and Colorado context.

QUESTION PRESENTED

Is it legal to produce and sell industrial hemp-derived CBD oil in the United States without violating the Controlled Substances Act (CSA)? Is industrial hemp-derived CBD oil legal to sell in Colorado?

SCOPE/ASSUMPTIONS

The legal analysis contained herein addresses the federal statutory and regulatory provisions of the United States Controlled Substances Act, Title 21, Chapter 13, U.S.C.S., pertaining to the sales and distribution of cannabidiol oils and products. This question is specifically targeted to cannabidiol (CBD). Importantly, this analysis is based on the assumption that the raw product industrial hemp material are lawfully imported[1] from international markets, and the CBD oil/products are produced and manufactured within the United States from said import materials.

This letter is limited to the analysis of the CSA, and does not address, nor does it consider, the rules or regulations governing the Food and Drug Administration, the Federal Food, Drug, and Cosmetic Act (often abbreviated as FFDCA, FDCA, or FD&C), or Investigational New Drug (IND) rules, as they may or may not be applicable.

SHORT ANSWER

[1] Lawfully imported under approved tariff codes to its FDA registered and certified facility in the United States.

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Yes. The sale, production and distribution of CBD oils/products derived from imported raw material industrial hemp is legal under the CSA. The sale of industrial hemp-derived CBD oil is legal in the state of Colorado and not subject to regulation by the Department of Revenue's Marijuana Enforcement Division.

BACKGROUND

Industrial hemp is a commonly used term for non-psychoactive, non-drug varieties of the species Cannabis sativa L. that are cultivated for industrial rather than drug purposes. Industrial hemp plants grown in Canada, China, and Europe are bred to contain less than 0.3% and 0.2% by weight of tetrahydrocannabinol (THC), the psychoactive element, in the upper portion of the flowering plant, respectively, versus the drug marijuana varieties, which typically contain 3 to 25% THC in their flowers.

Cannabidiol is naturally occurring in industrial hemp and is devoid of psychoactive effect. As set forth herein, natural cannabinoids from industrial hemp are specifically exempt from the CSA. Since natural cannabinoids are found in all industrial hemp products, and industrial hemp products are found in many grocery store shelves nationwide, industrial hemp oils are the easiest legal manner in which to obtain CBD. Products made from industrial hemp are found in retail stores nationwide, thanks to a federal exemption to the definition of "marijuana," as explained below.

DISCUSSION

1. **Legal Definition of Marijuana**

Since 1937, federal law has specifically provided that industrial hemp fiber, sterilized seed and seed oil are exempt from the definition of "marihuana" and are thus not controlled substances under that law. The CSA's predecessor statute with respect to regulation of marijuana was the Marihuana Tax Act of 1937, which set forth a definition of marijuana that the CSA adopted without change. The Marihuana Tax Act specifically differentiated between drug marijuana and industrial hemp through a system under which drug marijuana varieties of cannabis were taxed at a level so high as to effectively prohibit their production, while non-drug industrial hemp cultivation was assessed a minimal tax in order to permit and encourage its production.

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Under the CSA, illegal marijuana does not include industrial hemp fiber, seed or oil. The definition of "marihuana" specifically excludes "the mature stalks of such [cannabis] 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…." 21 U.S.C. § 802(16).

In 1970 Congress adopted the Controlled Substances Act (codified at 21 U.S.C. § 801 et seq.) repealing the 1937 tax statute, but carrying forward its definition of marijuana into the present criminal ban on production, sale and possession. *United States v. Walton*, 514 F.2d 201, 203 (D.C. Cir. 1975). In 1937 Congress had indicated in legislative history that production for industrial uses would be protected (primarily by a relatively low tax), see S. Rep. No. 75-900, at 4; Smith, 269 F.2d at 218-20. Congress' main vehicle for protecting industrial use plant production in 1937 was not its basic definition of "marijuana," which included plants ultimately destined for industrial use; it was the complex scheme of differential tax rates and other requirements for transfers.

The CSA makes it illegal to manufacture, distribute, dispense, or possess any controlled substance except as authorized by the CSA. 21 U.S.C. §§ 841(a)(1), 844(a). A controlled substance is anything listed in a schedule under the CSA. *Id.* at § 802(6). The CSA establishes five "schedules" of controlled substances differentiated by the scheduled drugs' potential for abuse, usefulness in medical treatment, and potential consequences if abused. To be placed on Schedule I, a drug or substance must have a "high potential for abuse," must have "no currently accepted medical use in treatment in the United States," and there must exist "a lack of accepted safety for use of the drug or other substance under medical supervision." 21 U.S.C. § 812(b)(1).

"Marihuana" (marijuana) and "tetrahydrocannabinols" (THC) are both listed on Schedule I. *Id.* at § 812(c)(Schedule I)(c)(10), (17)). Given the 1937 intent to protect industrial uses and the carrying forward of the definition, the 1970 statute should also be read to protect production for industrial uses by interpolating this distinction between psychoactive and non-psychoactive strains of cannabis sativa.

Under the CSA, "marijuana" is defined--not by the DEA but by Congress--as follows:

> [A]ll parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber

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> 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.

21 U.S.C. § 802(16)(*emphasis added*).

The Ninth Circuit explored whether industrial hemp was covered by the CSA in a series of cases. *In Hemp Indus. Ass'n. v. DEA*, 357 F.3d 1012 (9th Cir. 2004), the Court ruled that naturally occurring cannabanoids in industrial hemp foods, including oil, were never scheduled under the CSA; therefore, the DEA has no jurisdiction. This means that CBD, and even THC, when in industrial hemp oil, are legal.

The Court concluded: "[a]s in the case of poppy seeds commonly consumed on bagels and expressly exempted from the CSA, that come from a non-drug variety of, but the same species as, the opium poppy…non-psychoactive hemp seed products do not contain any controlled substance as defined by the CSA..." 357 F.2d at 1017. The Court further found that "[t]he non-psychoactive hemp in…products is derived from the 'mature stalks' or is 'oil and cake made from the seeds' of the Cannabis plant, and therefore fits within the plainly stated exception to the CSA definition of marijuana. … Congress knew what it was doing and its intent to exclude non-psychoactive hemp from regulation is entirely clear." *Id*. at 1018.

When the Hemp Industries Association defended industrial hemp's exempt status in Federal Court in 2004, the DEA declined to challenge this ruling, which is why there continues to be a wide variety of industrial hemp products on the market today. *See Hemp Industries Association v. DEA*, 357 F.3d 1012 (9th Cir. 2004). If the DEA had really been trying to ban industrial hemp foods, it would have appealed; which it did not. Accordingly, CBD producers and distributors can rely on this case to support their claims that sale of CBD oil is not prohibited by the CSA.

Congress was aware of the presence of trace amounts of psychoactive agents (later identified as THC) in the resin, stalks, oil or cake of non-psychoactive industrial hemp when it passed the 1937 "Marihuana Tax Act," and when it adopted the Tax Act marijuana definition in the CSA. As a result, when Congress excluded from the definition of marijuana such portions of a cannabis plant.

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Thus, imported industrial hemp stalks, fibers, oils, or cakes derived from a hemp plant imported internationally are not legally defined as marijuana and are, thus, not unlawful to possess. Such is not "marijuana." Here, CBD products sold by iPuff Vape LLC, made from the non- psychoactive hemp, is derived from the "mature stalks" or is "oil and cake made from the seeds" of the cannabis plant and, therefore, these products fit within the plainly stated exception to the CSA definition of "marijuana."

2. **Definition of THC**

Thus far, it is clear that CBD products produced from the stalks and fibers of a lawfully imported industrial hemp plant is lawful, as it falls outside of the definition of "marijuana." But what about THC? Industrial hemp plants do contain trace amounts of (not to exceed .3%) THC.

The definition of "THC" under the CSA includes only synthetic THC. 21 C.F.R. §1308.11(d)(27). THC is defined there as "[s]ynthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers...." The lawful definition of THC expressly excludes THC that is naturally occurring in the stalks and fibers of a lawfully imported industrial hemp plant. Additionally, the controlled substances listing of THC is different from the listings for DMT, mescaline, psilocybin, and psilocyn, the definitions for which are not limited to synthetic forms of the drugs. *See* 21 C.F.R. § 1308.11(d).

In Hemp Indus. Ass'n. v. DEA, supra, the Court held that the DEA could regulate products containing natural THC if it is contained within marijuana, and can regulate synthetic THC of any kind. But they cannot regulate naturally occurring THC not contained within or derived from marijuana, i.e., non-psychoactive hemp products, because non-psychoactive hemp from the stalks and fibers of such a plant is not included in Schedule I. The Court concluded that the "DEA has no authority to regulate drugs that are not schedule…." *Id.* at 1018.

Furthermore, the Court concluded, "[I]f naturally-occurring THC were covered under THC, there would be no need to have a separate category for marijuana, which obviously contains naturally-occurring THC. Yet Congress maintained marijuana as a separate category." *Hemp Indus. Ass'n. v. DEA*, 357 F.3d 1012, 1014 (9th Cir. 2004)(*quoting Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1089 (9th Cir. 2003).

In summary, under the CSA, the DEA can regulate foodstuffs and related products containing

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natural THC if it is contained within "marijuana," and can regulate synthetic THC of any kind. But they cannot regulate naturally-occurring THC not contained within or derived from marijuana--i.e., non-psychoactive industrial hemp products--because nonpsychoactive industrial hemp is not included in Schedule I, as set forth above. This is because statutes must be interpreted strictly and pursuant to their specific terms, and because the DEA has no authority to regulate drugs that are not scheduled. iPuff Vape LLC's products do not contain the "synthetic" "substances or derivatives" that are covered by the definition of THC, and nonpsychoactive industrial hemp is explicitly excluded from the definition of marijuana.

3. **Definition and Regulation under Colorado Law**

With the historic passage of Amendment 64 in 2012, Colorado ushered in a new era for marijuana, but also impacted the use of hemp and CBD in the state by defining "industrial hemp" and adopting the CSA definition of marijuana, excluding hemp products from state oversight. Colo. Const. art. XVIII, §§16(2)(d) and 16(2)(f).

"Industrial Hemp" is defined as "the plant of the genus cannabis and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration that does not exceed three-tenths percent on a dry weight basis." *Id.*

Finally, the State of Colorado has gone a step further and authorized the cultivation of industrial hemp and regulation of the same through the passage in 2013 of Senate Bill 241 and the Industrial Hemp Farming Act of 2014, also known as H.R. 525, in 2014. The Colorado Department of Agriculture is charged with implementing and administering that program.

CONCLUSION

In conclusion, iPuff Vape LLC's CBD products, as set forth herein, are wholly lawful under both the CSA and Colorado Law.

Sincerely,

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