kightlaw

February 15, 2019

Dr. Shawn E. Seitz
President and CEO
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25 Porter Rd., Ste. 210
Littleton, MA 01460

Via Email: drseitz@alphatechpet.com

Re: Legal Status of Hemp, Hemp Extract, and Cannabidiol (CBD)

Dear Dr. Seitz:

This letter addresses the legal status of hemp and its derivatives, including cannabidiol (CBD), in the United States of America (USA). It is a follow up to, and slightly revised version of, my letter on this same subject dated January 4, 2019.[1] The specific legal issue addressed in this letter is whether minimally processed raw hemp and hemp extract including CBD and other phytonutrients derived from hemp are lawful to transport, process, sell, and use in the USA.

Subject to the qualifications and limitations set forth in this letter, it is our opinion that minimally processed raw hemp and hemp extract including CBD are exempt from the federal Controlled Substances Act (CSA)[2] and are lawful to transport, process, sell, and use in the USA.

This opinion is based on the CSA and its drug schedules, the hemp provisions of the Agricultural Improvement Act of 2018[3] (2018 Farm Bill), and the industrial hemp provisions of the 2014 Farm Act[4] (2014 Farm Act). Additionally, our opinion is based on statements of policy from the Department of Justice (DOJ) and Drug Enforcement Agency (DEA) and the Food and Drug Administration (FDA), congressional appropriations Acts, and judicial precedent. Finally, with respect to the products sold by Alpha Tech Pet, Inc., it is based on product information provided to us regarding the source of its hemp. Specifically, Alpha Tech Pet, Inc. manufactures and sells animal products containing hemp extract as discussed in this letter. This opinion letter is prepared solely for Alpha Tech Pet, Inc. according to the pertinent facts. To the extent that any of the materials we reviewed contained legal opinions we did not take them into consideration. The opinions expressed in this letter are our own.

I. INTRODUCTION AND DEFINITIONS

[1] The revisions are in response to developments regarding CBD isolate, none of which apply to the products addressed in this letter. The discussion regarding CBD isolate has thus been omitted to avoid confusion except where necessary for context.

[2] 21 U.S. Code § 801 *et seq.*

[3] https://docs.house.gov/billsthisweek/20181210/CRPT-115hrpt1072.pdf

[4] 7 U.S. Code § 5940 - Legitimacy of industrial hemp research, sometimes referred to as "Section 7606" after the section authorizing it in the bill that became the Act.

In order to discuss the legal status of hemp, hemp extract, and CBD under federal law it is necessary to distinguish the terms “cannabis”, “marijuana”[5], “industrial hemp”, and “hemp”. This letter is concerned with “hemp” as that term is defined in the Hemp Farming Act of 2018.[6]

Cannabis is the genus of the scientific name of the plant Cannabis sativa L. The term “cannabis” is not a legal term of art. It encompasses lawful industrial hemp, lawful hemp, and illegal marijuana, all of which have statutorily defined meanings. All marijuana is cannabis; all industrial hemp is cannabis; and all hemp is cannabis. However, the opposite is not true: not all cannabis is marijuana, nor is all cannabis industrial hemp or hemp. Confusingly, the term “cannabis” is often used loosely and colloquially as a synonym for “marijuana”. Marijuana reform advocates generally prefer the term “cannabis” because of its botanical significance and also due to the fact that the term “marijuana” is historically associated with prohibition and racial injustice.[7] The DEA also often employs the term “cannabis” when it means “marijuana”, a practice that may be a deliberate method for sowing confusion. When it does so, it usually (though not always) qualifies its usage by clarifying that it is only referring to substances that fall within the CSA definition of marijuana.[8] In fact, the widespread use of a legally undefined term that encompasses both lawful and unlawful substances is a primary cause of the confusion surrounding the legal status of hemp, hemp extract, and CBD.

Marijuana is defined in the CSA as “*all 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 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.*”[9] The statute carves out an exception to the definition of cannabis for the “mature stalks”[10], “sterilized seed”, and non-resinous products derived from them, such as CBD.

Industrial hemp is a type of cannabis that is lawful when grown under a state pilot program pursuant to the 2014 Farm Act, which created the first exception to marijuana for “*the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9-*

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[5] The CSA uses the antiquated spelling “marihuana”. I will use the contemporary spelling, “marijuana”, in this letter.

[6] https://www.congress.gov/115/bills/s2667/BILLS-115s2667pcs.pdf

[7] *See, eg*, "*Marijuana: is it time to stop using a word with racist roots?*" The Guardian, January 29, 2017: https://www.theguardian.com/society/2018/jan/29/marijuana-name-cannabis-racism

[8] *See, eg*, Footnote 5, above. *See also*, “Clarification of the New Drug Code (7350) for Marijuana Extract”, March 14, 2017, which is discussed below. It states the following in reference to the “Marijuana Extract Rule” (discussed below), “*The new drug code (7350) established in [the Rule] does not include materials or products that are excluded from the definition of marijuana set forth in the Controlled Substances Act (CSA). The new drug code includes only those extracts that fall within the CSA definition of marijuana. If a product consisted solely of parts of the cannabis plant excluded from the CSA definition of marijuana, such product would not be included in the new drug code (7350) or in the drug code for marijuana (7360).*”

[9] 21 U.S.C. § 802(16)

[10] Further adding to the confusion regarding nomenclature, the term “hemp” has been used extensively by the DEA to refer to the mature stalks of the cannabis plant. In this context it is not a legal term of art, but a colloquial expression.

tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis" that is grown pursuant to a state's industrial hemp pilot program. The industrial hemp provisions of the 2014 Farm Act (Section 7606 "Legitimacy of Industrial Hemp Research) clearly indicate that industrial hemp is exempt from the CSA by beginning with the phrase, *"Notwithstanding the Controlled Substances Act..."*. The fact that industrial hemp is not controlled was confirmed in an April 30, 2018 ruling by the Ninth Circuit Court of Appeals, which found: "*The [2014 Farm Act] contemplates potential conflict between the Controlled Substances Act and preempts it.*"[11] Industrial hemp is lawful under federal law and may be transported across state lines. Industrial hemp is used for its oils and its fibers in applications ranging from construction to textile manufacturing to food production to health and wellness products. Industrial hemp cultivation under the 2014 Farm Act is scheduled to phase out and be replaced by hemp cultivation under the 2018 Farm Bill.

Hemp is a type of cannabis plant that is defined at Section 297(a) of the 2018 Farm Bill, enacted on December 20, 2018. Congress has essentially traded the term "industrial hemp", for the simpler term "hemp", made the definition more specific to include derivatives of the plant, and removed it from the purview of a state pilot program. Hemp 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 concentration of not more than 0.3 percent on a dry weight basis.*" Notably, the legal definition of hemp expressly includes "extracts" and "cannabinoids".

II. HEMP AND HEMP EXTRACTS ARE LAWFUL UNDER THE 2018 FARM BILL

The 2018 Farm Bill will restructure the future of hemp farming in the United States over the next year and a half. Most importantly, the 2018 Farm Bill contains a CSA exemption for hemp "and any part of that plant" *(SEC 12619 "Conforming Changes to Controlled Substances Act")*, stating in pertinent part:

> *(a)(2) The term 'marihuana' does not include— ''(i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946*
>
> *(b) Tetrahydrocannabinol.—Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)), is amended in subsection (c)(17) by inserting after ''Tetrahydrocannabinols'' the following: "except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946)".*

The federal CSA exemption from marijuana for "industrial hemp" was initially created by the 2014 Farm Act. This was the first federal law to create a lawful type of cannabis called "industrial hemp", which was lawful when cultivated for research purposes by "*an institution of higher education*" or "*a State department of agriculture".* An "agricultural pilot program"

[11] *Hemp Indus. Ass'n v. United States DEA*, 720 Fed. Appx. 886, 887 (9th Cir. 2018) (HIA v DEA)

means "*a pilot program to study the growth, cultivation, or marketing of industrial hemp.*" Although the 2014 Farm Act expired on September 30, 2018, the industrial hemp provisions required specific repeal.

The 2018 Farm Bill accomplishes this repeal by phasing out the pilot programs while the Secretary issues new regulations. During the phase out period, and until the United States Secretary of Agriculture (Secretary) establishes a federal regulatory plan, the pilot program structure remains intact. This means that most, and perhaps all, of the domestically cultivated hemp in 2019 will be grown under a state pilot program as contemplated by the 2014 Farm Act. The definition for industrial hemp remains intact under the 2014 Farm Act while the pilot programs are still operational.

The 2018 Bill solidifies that the CSA exemption initiated in the 2014 Farm Act applies to newly classified "hemp". It goes further to ensure that the exemption applies to the small amounts of THC that can sometimes be found in hemp, which is similarly exempt from the CSA.

The 2018 Farm Bill operates by amending the Agricultural Marketing Act of 1946 (*7 U.S.C. 1621 et seq.)* and adding Subtitle G "Hemp Production" to allow for regulation of hemp as an agricultural commodity. *(SEC. 10113. Hemp Production)*. The definitions and procedures for creating the new regulatory scheme can be found in S.2667[12], which is cited as the "Hemp Farming Act of 2018". They are also included in the Farm Bill itself. Under the 2018 Farm Bill definition of "hemp", hemp extracts are similarly lawful provided that they do not contain delta-9 THC concentrations in excess of 0.3%.

The 2018 Farm Bill vests in the Secretary the authority to issue federal regulations and guidelines for hemp. The Bill also requires that the Secretary conduct a study *"…to determine the economic viability of domestic production and sale of industrial hemp"*. This study includes a review of each individual agricultural pilot program. The Secretary must submit a report to congress within one hundred and twenty (120) days of the 2018 Farm Bill's enactment (ie, by April 18, 2019).

After the Secretary submits its report, a state may submit a proposed "State and Tribal Plan" (Plan) to regulate industrial hemp. Upon receipt of a Plan the Secretary must reply within sixty (60) days by either approving or denying it. There is a remediation clause whereby a State may amend its Plan based on the recommendations of the Secretary. Section 297(c) requires the Secretary of Agriculture to promulgate a federal plan to cultivate hemp and a licensing structure to implement it. States that do not propose a Plan, or are unable to obtain approval of a Plan, will by default be regulated by the federal plan.

Importantly, a state cannot simply opt out and have no program for regulating hemp. Under the 2018 Farm Bill, a state can either submit a Plan or be regulated by the federal plan. The Secretary must review a state sponsored plan against a series of criteria (eg., procedure for tracking of farmland planted with hemp, testing for THC content, disposal of non-compliant

[12] https://www.congress.gov/115/bills/s2667/BILLS-115s2667pcs.pdf

plant material, compliance with law enforcement). The definition of "States" includes the District of Columbia, Indian Reservations in the United States, and any other territory or possession of the United States.

The 2018 Farm Bill unequivocally creates a legal market for hemp in all 50 states and allows for interstate commerce of hemp. *(SEC. 10114. Interstate Commerce).* States without approved self-regulatory schemes for hemp are open for hemp and hemp extract as a commodity within their borders. Section 10114 states:

> *a. Rule of construction*
> *Nothing in this title or an amendment made by this title prohibits the interstate commerce of hemp (as defined in section 297A of the Agricultural Marketing Act of 1946 (as added by section 10113)) or hemp products.*
>
> *b. Transportation of hemp and hemp products*
> *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 (as added by section 10113) through the State or the territory of the Indian Tribe, as applicable.*

Once the provisions of the 2018 Farm Bill have been fully implemented, hemp cultivation will be governed by federal regulations unless a state submits a regulatory plan that is approved by the Secretary. Unlike industrial hemp under the 2014 Farm Act, hemp under the 2018 Farm Bill is lawful throughout the country. A state may regulate it; however, a state may not prohibit it outright. Currently, no federal regulations regarding hemp have been enacted, or even proposed. No state plans have been approved.

States with pilot programs may continue to produce and regulate hemp until the hemp provisions of the 2014 Farm Act are supplanted by the federal plan to be issued by the Secretary. Cultivators and processors licensed under state pilot programs established under the 2014 Farm Act remain compliant with federal law when they adhere to pilot program regulations in an individual state.

III. HEMP EXTRACTS INCLUDING CBD ARE LAWFUL

The legal status of CBD, or any other cannabinoid, depends on its source. This is referred to as the "Source Rule". Specifically, the legal status of CBD and other cannabinoids depends on whether its source material is lawful hemp or illegal marijuana.[13] Under the Hemp Farming Act, cannabinoids derived from hemp, including CBD, are expressly lawful. By contrast, cannabinoids from marijuana are not lawful. The FDA recently approved Epidiolex, an oral solution of CBD derived from marijuana. This FDA approval prompted the DEA to reschedule

[13] "*[A]ny material, compound, mixture, or preparation other than Epidiolex that falls within the CSA definition of marijuana set forth in 21 U.S.C. 802(16), including any non-FDA-approved CBD extract that falls within such definition, remains a schedule I controlled substance under the CSA.*" Federal Register / Vol. 83, No. 189, Page 48952

Epidiolex from Schedule I (most restrictive) to Schedule V (least restrictive).[14][15] While this is a positive development for cannabis legislation generally, it does not impact CBD from hemp, which has never been included on any federal drug schedule.

IV. DEA MARIHUANA EXTRACT RULE, CLARIFICATION, DIRECTIVE, AND COURT FILINGS

Based on the definition of hemp under the Hemp Farming Act, extracts from hemp, including CBD, are lawful in the USA notwithstanding a DEA rule regarding marijuana extracts. On December 14, 2016 the DEA published a Final Rule called "Establishment of a New Drug Code for Marihuana Extract".[16] The DEA Rule creates the following definition for "marihuana extract", which became effective January 13, 2017: "*An extract containing one of more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant.*"

The DEA Rule caused a false impression in the media that it made all CBD illegal because it failed to make clear that it did not apply to extracts derived from forms of cannabis that were exempt from the CSA definition of marijuana. The DEA later clarified on several occasions that the new regulation merely reiterated the fact that cannabinoids derived from marijuana are illegal, but that they are lawful when derived from a lawful source. The Hemp Farming Act expressly clarifies that extracts of hemp, including extracts containing one or more cannabinoids, are lawful.

V. CBD UNDER THE FOOD, DRUG, AND COSMETIC ACT

Products containing CBD are subject to the Food, Drug, and Cosmetic Act (FDA Act).[17] They may not be marketed as dietary supplements[18], and no claims may be made about their ability to "*diagnose, cure, mitigate, treat or prevent disease"* (emphasis added). *[21 U.S.C. § 321(g)(1)(B)]* The FDA currently holds the position that adding CBD isolate to food that enters interstate commerce violates the FDA Act.[19] This is based on the fact that CBD is not on the FDA's New Dietary Ingredient (NDI) list and was not marketed as a food prior to the initiation of drug trials for investigative new drugs (IND) in which it is an active compound. Notably, the FDA position is not an official rule; it appears as a response to a question on an FAQ page, and the FDA has not taken any action to enforce its position.

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[14] On September 28, 2018, the DEA rescheduled Epidiolex from Schedule I (the most restrictive) to Schedule V (the least restrictive): "*By virtue of this order, Epidiolex (and any generic versions of the same formulation that might be approved by the FDA in the future) will be a schedule V controlled substance. Thus, all persons in the distribution chain who handle Epidiolex in the United States (importers, manufacturers, distributors, and practitioners) must comply with the requirements of the CSA and DEA regulations relating to schedule V controlled substances.*" Federal Register / Vol. 83, No. 189, Page 48952

[15] The DEA list of controlled substances can be found at the following URL: https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf

[16] 21 CFR Part 1308 (DEA Rule)

[17] 21 USC § 301 *et seq*.

[18] FDA Act [21 U.S.C. § 321(ff)(3)(B)(ii)]

[19] http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#dietsuppsexclude

On December 20, 2018, shortly after the 2018 Farm Bill was signed into law, the FDA released a "Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds" (Statement)[20]. Although the Statement received considerable media attention and sparked concern throughout much of the hemp industry, it did not include any changes in the FDA's longstanding position described above. In fact, and despite the fresh context, the only new information it provided was an assertion that the FDA is considering modifying its position and employing a procedure which would expressly authorize the use of CBD as an ingredient in food. Specifically, the Statement asserts:

> "*[P]athways remain available for the FDA to consider whether there are circumstances in which certain cannabis-derived compounds might be permitted in a food or dietary supplement. Although such products are generally prohibited to be introduced in interstate commerce, the FDA has authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement. We are taking new steps to evaluate whether we should pursue such a process. However, the FDA would only consider doing so if the agency were able to determine that all other requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients.*"

Regardless of the FDA's position on CBD, an important distinction involves the sale of hemp extract in which CBD is present as a naturally occurring compound among an array of other naturally occurring compounds. It is our opinion that this is lawful, notwithstanding the IND status of CBD. This is because food and dietary supplement products that contain naturally occurring compounds, such as CBD, that have been approved as IND and which were not present in isolated form in the food supply prior to initiation of drug trials are not prohibited when they are present in naturally occurring levels and the food or dietary supplements were marketed prior to the initiation of drug trials.[21] For this reason, FDA regulation of hemp extract is necessarily different (ie, less restrictive) than its regulation of CBD isolate. This is due to the fact that hemp extract contains CBD and other naturally occurring cannabinoids, terpenes, and plant compounds. Such extracts are different in kind from CBD isolate (and Epidiolex). Additionally, and unlike CBD isolate, they have been consumed safely as food and medicine in the USA and other countries for centuries.[22]

Additionally, the World Health Organization (WHO) has concluded after two extensive reviews that CBD is safe, non-psychoactive, and incapable of producing a "high" at any dose.[23] The

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[20] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm

[21] See, eg. *Pharmanex v. Shalala*, 221 F.3d 1151 (10th Cir. 2000)

[22] See, eg, "Medicinal Cannabis: History, Pharmacology, And Implications for the Acute Care Setting" by Mary Barna Bridgeman, PharmD, BCPS, BCGP and Daniel T. Abazia, PharmD, BCPS, CPE, published in the March 2017 edition of Pharmacy and Therapeutics, a peer reviewed journal. "In the U.S., cannabis was widely utilized as a patent medicine during the 19th and early 20th centuries, described in the United States Pharmacopoeia for the first time in 1850."

[23] https://www.forbes.com/sites/janetwburns/2018/03/18/who-report-finds-no-public-health-risks-abuse-potential-for-cbd/#6208a9fa2347

WHO's first round pre-review was overwhelmingly positive, finding that "*there is no justification for CBD to be included in the anti-drug treaties…*" and validating the effectiveness of the compound in therapeutic applications. *(id.)* The review also found no evidence of risk for dependence or abuse. The second review took place in May, 2018. It confirmed the findings in the initial review.[24] According to its mission statement, the FDA is "*responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation."*[25] Given this mission, the WHO's findings, and the FDA's own acknowledgement in the Statement of "*the potential opportunities that cannabis or cannabis-derived compounds could offer*", it appears unlikely that the FDA will take enforcement action regarding the use of CBD in products that are properly manufactured, otherwise safe and compliant, and that do not make improper claims.

VI. AVMA POSITION ON HEMP EXTRACT AND CBD

The American Veterinary Medical Association (AVMA) is the national regulatory body for the practice of veterinary medicine. It is the analogous body to the American Medical Association (AMA). It does not currently hold an official position on hemp extract or CBD. In September 2017 the AVMA Council on Therapeutic Agents and the Clinical Practitioners Advisory Committee took an interest in marijuana use in veterinary medicine. (Note, "marijuana" not "hemp".) This was largely in response to a position paper issued by the Colorado Veterinary Medical Association (CVMA) on this topic. In the paper, the CVMA states unequivocally that it is illegal in the state of Colorado for a veterinarian to prescribe marijuana for animal use. The CVMA is quoted in its paper stating the position of the AVMA with regard to Cannabinoid compounds:

> "*The American Veterinary Medical Association does not have a position statement on the use of marijuana and marijuana products and offers this advice: Veterinarians making treatment decisions must use sound clinical judgment and current medical information, and must be in compliance with federal, state and local laws and regulations…. To date, there are no known scientifically proven therapeutic uses for cannabinoids in companion animals."*

The CVMA paper, and the AVMA investigation, is in response to the large number of pet owners asking their veterinarians about medical marijuana use for their pets. This is largely due to marijuana's recognized medical applications in humans for a variety of disease.

As with the AMA, the AVMA has Prescription Drug Monitoring Programs (PDMP) in place in many states. The purpose of these programs is to monitor the administration of certain drugs prescribed to dogs that could be misused by humans (specifically opiates). In 34 states, veterinarians are exempt from these PDMP programs. Since CBD is an IND due to the recent

[24] http://www.who.int/medicines/access/controlled-substances/WHOCBDReportMay2018-2.pdf?ua=1

[25] https://www.fda.gov/aboutfda/whatwedo/

approval of Epidiolex, veterinarians that are not exempt from the PDMP programs may have to report use of it in animals.[26] However, since hemp extract is not a prescription drug, veterinarians are not required to report anything about administration of products containing it.

Veterinarians are not able to prescribe CBD to their animal patients. However, it is lawful for veterinarians to have frank conversations with human pet owners about the potential benefits of CBD and to sell products containing hemp extract in their offices. Making a recommendation for a non-regulated substance is different than prescribing a scheduled or FDA approved drug. Hemp extract is not a federally scheduled drug, nor is it an IND. While veterinarians should refrain from making any specific claims about the ability of CBD products to produce any specific result, it is not illegal nor ill-advised for them to have frank conversations that may help pet owners make informed decisions about treatment options for companion animals suffering from disease. Additionally, it is lawful for them to sell products containing hemp extract.

VII. CONCLUSION

Based on the above analysis, our opinion is that minimally processed raw hemp and hemp extract including CBD and other phytonutrients derived from hemp are lawful to transport, process, sell, and use throughout the United States. The passing of the 2018 Farm Bill unequivocally legalized hemp and its derivatives throughout the country. For these reasons, Alpha Tech Pet, Inc.'s products are lawful.

Sincerely,

D. Rodney Kight, Jr.
Attorney

[26] Epidiolex is not currently indicated for treatment of animal diseases.