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April 11, 2017

Sisters of the Valley, LLC Attn. Christine Marie Meeusen 3144 G ST STE 125-205 Merced, CA 95340

Re: Cannabidiol opinion letter

Dear Sister Kate:

You have asked me to prepare an opinion letter for Sisters of the Valley, LLC ("Sisters" or "the Company") regarding the current legal status of cannabidiol ("CBD") in the United States of America ("USA") as it relates to the Company's operations and products.

It is my professional opinion that CBD which is sourced from a state which has enacted hemp laws in accordance with The Agricultural Act of 2014 ("the Farm Bill")¹ is legal under both Federal law and, to the extent applicable, the laws of the State in which it was sourced. Additionally, such CBD may be transported to, and sold in, any state without violating Federal law. Based on my understanding of its business operations, it is my opinion that the Company's CBD products are lawful and may be transported, processed, sold and used throughout the USA without violating Federal law.

This letter will first address the legal status of CBD and conclude by addressing the legal status of the Company's specific CBD products.

PART 1: IT IS LAWFUL TO SOURCE, DISTRIBUTE, AND SELL CBD FROM THE THE INDUSTRIAL HEMP PLANT

a. CBD extracted from certain parts of the cannabis plant are legal throughout the USA.

¹ This opinion is limited to the legal status of CBD in the USA. Accordingly, and unless otherwise noted, all legal references are to USA statutes, rules, court cases, etcetera.

CBD comes from Cannabis Sativa L ("cannabis"), which is illegal under the Federal Controlled Substances Act ("CSA"). 21 USC § 801 et seq. Cannabis is a Schedule I drug, which is the most restrictive class of drugs under the CSA. The following parts of cannabis are not included in the CSA definition:

"[T]he 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." 21 USC § 802(16)

CBD produced from any parts of the cannabis plant in the above list of exclusions is legal. In this letter I will refer to the parts of the plant listed above as "the excepted parts of the plant." The Drug Enforcement Administration ("DEA"), a Federal law enforcement agency under the Department of Justice ("DOJ"), is tasked with combating drug smuggling and use within the USA. It made this point explicit on March 14, 2017 when it issued the following statement:

"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)."² (emphasis mine)

Generally speaking, CBD is produced by the cannabis plant's trichomes, which are glandular hairs. Cannabis seeds contain little to no CBD; however, some mature stalks do appear to contain CBD. The primary legal obstacle to obtaining CBD from mature cannabis stalks is that, with the exception of hemp grown in accordance with the Farm Bill (see below), it is illegal under Federal law to grow cannabis. Even though the mature stalks are legal to possess, in order to become "mature" they must first go through a phase in which they are not fully developed and contain tetrahydrocannabinol ("THC") levels which are in violation of the CSA. Companies that are willing and able to extract

² This statement was issued as a clarification to the "Final Rule establishing a new Controlled Substance Code Number (drug code) for marijuana extract", issued December 14, 2016, and discussed further, below.

CBD from the stalks have, until very recently, had to do so outside of the United States to circumvent this problem. CBD extracted from the mature stalks of a lawfully cultivated industrial hemp plant are unqualifiedly legal

b. CBD obtained from hemp grown pursuant to a DEA permit is legal.

The DEA has the authority to issue permits to grow hemp. These licenses are rarely issued. Given the current status of the law regarding CBD as described herein, I do not recommend that the Company seek a DEA permit to cultivate or process hemp. It is a cumbersome process with a high likelihood of denial. The law, though evolving, offers more efficient and reliable ways to cultivate hemp and extract and sell CBD legally than by seeking a DEA permit.

c. CBD obtained from industrial hemp grown pursuant to the Farm Bill is legal within the state that it is grown.

In a provision of the Farm Bill called "Legitimacy of Industrial Hemp Research" Congress carved out an exception to the CSA's definition of cannabis for what it calls "industrial hemp", which it defines as "the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." 7 USC § 5940(b)(2)

According to the Farm Bill, a State department of agriculture³ may grow or cultivate industrial hemp if it satisfies two key elements. First, the industrial hemp must be grown or cultivated "for purposes of research conducted under an agricultural pilot program or other agricultural or academic research." Second, the growing or cultivating of industrial hemp must be "allowed under the laws of the State in which such institution of higher education or State department of agriculture is located and such research occurs." 7 USC § 5940(a)

³ I should note that the USA operates as a federal system in which the national government cogoverns with the fifty states. According to the US Constitution, the powers not granted to the National government (referred to as the "Federal Government") are reserved for the fifty States. Pursuant to the Supremacy Clause of the US Constitution (Article VI, Clause 2), in the event of a conflict between a valid Federal law (ie, one enacted and enforced by the the national government) and a State law the Federal law will prevail because it is the supreme law of the land. In this letter I will refer to the national laws as the "Federal" laws and to state laws generally as "State" laws.

Many states have established commercial industrial hemp programs. At first glance this approach may appear to conflict with the Farm Bill since it requires any hemp cultivation or growth to be for purposes of research conducted under an agricultural research pilot program. However, the Farm Bill does not dictate or otherwise specify the manner in which a State may carry out its pilot or other hemp related agricultural research program. In fact, the statute itself defines "agricultural pilot program" as "a pilot program to study the growth, cultivation, or marketing of industrial hemp." 7 USC § 5940(b)(1) (emphasis added) The proper construction of the Farm Bill's language is that Congress has given the states broad latitude to determine how they conduct their agricultural research pilot programs, including involving the commercial private sector to assist in researching the economic impact of lawful hemp cultivation. This view is bolstered by the fact that in a separate funding bill, discussed in subsection (d), below, Congress specifically prohibited Federal funds from being used to interfere with the sale of industrial hemp produced under the Farm Bill.

At the Federal level it is legal to extract CBD from the flower and leaves of the plant so long as it is sourced from "industrial hemp" as defined above from within a state that has enacted hemp laws that comply with the Farm Bill. CBD has never been Scheduled on the CSA. Unless otherwise addressed by statute, a component part of a lawful plant is itself lawful. CBD sourced from a lawful plant is lawful. This position is supported by the DEA's own "clarification", discussed in subsection (a), above, which states that components of the lawful part of the cannabis plant are themselves lawful. Industrial hemp grown pursuant to a State's hemp laws enacted in accordance with the Farm Bill is legal. As such, it naturally follows that CBD sourced from industrial hemp is also legal.

Despite the Farm Bill's explicit carve-out of industrial hemp from the CSA's prohibition on cannabis cultivation, it still limits CBD extraction, transport, and sale from parts of the industrial hemp plant that are not sourced from the excepted parts of the plant in two ways: (1) CBD can only be sourced in states that have enacted hemp laws in accordance with the Farm Bill; and (2) CBD cannot be transported to (or through), or sold in, other states, including states that have enacted their own laws regarding hemp. In other words, and aside from the excepted parts of the plant, the Farm Bill limits CBD extraction and sales to the specific Farm Bill compliant state from which the source hemp is grown.

⁴ See, e.g.., California, Colorado, Kentucky, North Carolina, Oregon, South Carolina.

d. Based on a 2015 Funding Bill CBD obtained from industrial hemp grown pursuant to the Farm Bill is legal at the Federal level and may be transported to, and processed, sold, and used, in any state in the USA that does not have laws expressly forbidding it.

Congressional intent with respect to the Farm Bill is explicitly set forth in the Consolidated and Further Continuing Appropriations Act of 2015 (Pub. L. 113-235, 128 Stat. 2130, §538 (2014)), which was initially re-authorized in the Consolidated Appropriations Act, 2016, (Pub. L. No. 114-113, 129 Stat. 1175 (§763)), and most recently re-authorized in December 2016 through April 28, 2017 (collectively, the "Funding Act") (Pub. L. No. 114-254), which states:

"None of the funds made available by this act or any other act may be used... to prohibit the transportation, processing, sale or use of industrial hemp that is grown or cultivated in accordance with section 7606 of the Agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated." (emphasis added)

Although this language does not explicitly amend the Farm Bill, it does forbid the use of Federal funds to enforce any law which would otherwise prohibit transporting, processing, selling, or using CBD in any state so long as the CBD was extracted pursuant to the provisions of the Farm Bill (which necessarily implies that the CBD was obtained from hemp that was legally grown in a state with Farm Bill compliant laws.) The practical effect of this clause is to make CBD legal on the Federal level throughout the USA. This is due to the decision in several recent cases involving a similar prohibition in funding bills, including the following two Ninth Circuit Court of Appeals cases: *U.S. v. Marin Alliance for Medical Marijuana (MAMM)*, Case No. 98-00086 ("Marin Alliance"), and *U.S. v. McIntosh*, Case No. 15-10122 (2016) ("McIntosh").

In *Marin Alliance* Judge Breyer found that a prior injunction prohibiting a California medical marijuana dispensary from operating was unenforceable except to the extent that the dispensary was not compliant with state law, even though the dispensary's acts were in direct violation of the CSA. The Court based its ruling on a funding bill (in that case § 538 of the 2015 Appropriations Act) which prohibited the Justice Department from expending any funds in connection with enforcement of any law that interfered with California's ability to implement its own state laws authorizing the use, distribution, possession, or cultivation of medical marijuana. Similarly, in *McIntosh* the Court held that the DOJ is prohibited from spending funds from a funding bill (in that case § 542 of the

Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, 129 Stat. 2242, 2332-33 (2015)) for the prosecution of individuals who engaged in conduct permitted by state medical marijuana laws and who fully complied with such laws.

In other words, Federal cannabis laws are unenforceable in California to the extent that they interfere with California's medical marijuana regime. This is because Congress prohibits the Justice Department from using any funds to enforce Federal cannabis laws against California state residents (including businesses) who are compliant with California's state laws regarding medical marijuana.

Because Congress prohibited Federal funds from being used to interfere with California's medical marijuana program, the practical effect of *Marin Alliance* and *McIntosh* was to legalize medical cannabis at the Federal level within the State of California. Similarly, any Federal laws restricting industrial hemp (and, consequently, CBD derived from industrial hemp) which was cultivated in accordance with the Farm Bill are unenforceable due to the restrictions set forth in the Funding Act. As a practical consequence, Farm Bill compliant CBD is legal throughout the USA, at least at the Federal level. As I discuss below, this prohibition also applies to states that receive Federal funds.

e. States may restrict CBD within their borders only if it was sourced from a non-excepted part of the plant and their enforcement agencies do not receive Federal funds.

Individual states may prosecute under state law if hemp and/or CBD is not legal within their borders, but only if the CBD in question was not sourced from the excepted part of the plant and they do not receive Federal funds. Although there is an argument to be made that state laws forbidding CBD are wholly unenforceable because Federal law preempts contradictory State law pursuant to Article VI, Clause 2 of the Constitution ("the Supremacy Clause"), my opinion is that the Funding Act only restricts acts by agencies (Federal or State) that receive Federal funds. As discussed above, these agencies may not use funds to prohibit CBD transportation, processing, sale, or use. Since the Funding Act does not contradict any specific State law or proscribe State law enforcement by agencies that do not receive Federal funds the Supremacy Clause is not likely implicated. In the event that the Company sources CBD from a non-excepted part of the cannabis plant it would be wise to confirm that CBD is not illegal under the laws of any State in which it intends to sell CBD or be certain that the relevant enforcement agencies in the state at issue receive Federal funds and are thus subject to the provisions of the Funding Act.

Given the Company's intention to operate on a national level throughout the USA I recommend that it source its CBD solely from the industrial hemp plant in a state that has authorized cultivation of industrial hemp pursuant to the Farm Bill. This will provide a sort of "double assurance" at the Federal level, and where applicable, at the individual state level: (1) the CBD is legal because it is lawfully sourced, and (2) even if it was otherwise illegal (see discussion of the DEA Rule in subsection g, below), no Federal funds can be used to prohibit its actions since it was lawfully sourced pursuant to the Farm Bill, thus making it de facto legal under the holdings in *Marin Alliance*, *McIntosh*, and other similar cases interpreting Congressional funding bills. I reiterate that CBD may be illegal under state law in states that do not receive Federal funding for their drug interdiction programs⁵, have not enacted hemp laws, and that explicitly ban cannabis.⁶

f. CBD sourced from a non-psychoactive hemp plant imported from abroad is legal throughout the USA at both the Federal and State levels.

Non-psychoactive hemp⁷ and its products containing little to no THC are legal to import and sell in the *United States. Hemp Industries Association, et al, v. Drug Enforcement Administration*, 333 F.3d 1082 (9th Cir. 2003) and *Hemp Industries Association, et al, v.*

⁵ As a practical matter, it is likely that all states receive Federal funding for their drug interdiction programs, thus making lawfully sourced CBD pursuant to the Farm Bill de facto lawful at the state level in all fifty states for the same reason that it is de facto legal at the Federal level. However, since I have not researched this issue as it pertains to every state in the USA I cannot give my opinion on this specific issue.

⁶ I should note that since the Company operates out of California, a state in which its activities are lawful, is compliant with Federal law, and Federal funds cannot be otherwise used to interfere with its activities, this issue is primarily significant to the Company's customers in states where cannabis is illegal, no hemp laws have been enacted, and that do not receive Federal funds. Customers fitting this specific profile may be violating state law by purchasing products which are unlawful in their states. Under these circumstances, a state will have great difficulty prosecuting an out of state company for violations of state law.

⁷ The term "non-psychoactive hemp" is a term employed by the Ninth Circuit Court of Appeals: "We refer to hemp stalks, fiber, oil and cake made from hemp seed, and sterilized hemp seed itself — i.e., those substances excluded from the definition of marijuana under 21 U.S.C. § 802(16) — as "non-psychoactive hemp." A "psychoactive" substance is one "affecting the mind or behavior." Merriam-Webster Dictionary.... The non-psychoactive hemp used in Appellants' products is derived from industrial hemp plants grown in Canada and in Europe, the flowers of which contain only a trace amount of the THC contained in marijuana varieties grown for psychoactive use." Hemp Indus. v. DEA, 357 F.3d 1012 (9th Cir. 2004) Although admittedly vague, this definition taken as a whole seems to imply that the flowers of industrial hemp plants which contain only trace amounts of THC are included in the definition of "non-psychoactive hemp", and products that derived therefrom are thus legal.

Drug Enforcement Administration, 357 F.3d 1012 (9th Cir. 2004) (collectively, "Hemp Indus.") Hemp Indus. involved a dispute between manufacturers of hemp products and the DEA over three DEA rules regarding hemp and THC. The primary rule at issue for our purposes was the first one, which purported to interpret both the CSA and the DEA regulations to ban all naturally-occurring THC, including the THC found in hemp seed and oil, on Schedule I. 66 Fed. Reg. 51,530 (October 9, 2001) This rule would have made it illegal for hemp manufacturers to produce and sell their products, even ones that contained only trace amounts of THC.

The 9th Circuit Court of Appeals found that the DEA exceeded its authority in enacting this rule and struck it down as void and unenforceable. Although from a technical perspective *Hemp Indus*. is about regulatory procedure and what constitutes an "interpretive rule", which requires one set of procedures to enact, versus a "legislative rule" which requires different and more cumbersome procedures to enact, the practical effect of the cases was to strike down the DEA's rule banning hemp products that contain only trace amounts of naturally occurring THC. This opened the door for companies to import hemp and products derived from hemp (such as CBD and hemp oil) from countries that allow it and to sell them throughout the USA. (I discuss *Hemp Indus*. in a slightly different context and in more depth in the next section.)

g. A recent DEA rule regarding "marihuana extract" and CBD does not override or change the legal nature of lawfully sourced CBD as described above.

On December 14, 2016 the DEA published a Final Rule called "Establishment of a New Drug Code for Marihuana Extract" 21 CFR Part 1308 ("the DEA Rule") The DEA Rule creates the following definition for "marihuana extract", which becomes 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."

In Volume 81, Number 240, Page 90194 of the Federal Register the DEA stated that "[e]xtracts of marihuana will continue to be treated as Schedule I controlled substances" under the CSA. Schedule I is the most restrictive schedule in the CSA. It is reserved for drugs, substances, or chemicals with no currently accepted medical use and a high po-

⁸ The DEA's spelling of what is now commonly referred to as "marijuana" is antiquated. I will spell it "marijuana" in this letter in accordance with the modern usage.

tential for abuse. 21 USC § 812(b)(1) News of the DEA Rule spread quickly once it was released. Major media outlets responded by interviewing DEA representatives. For example, DEA spokesman Russell Baer told Bloomberg that "extracts or derivatives from the cannabis plant are Schedule I controlled substances—just like the plant itself. There is widespread illegal distribution of purported CBD products—regardless if they are derived from the marijuana plant or hemp plant." Bloomberg, December 21, 2016: "Lacing Dog Treats With Cannabis Is Big Business", by Polly Mosendz. In another interview, Baer said the following:

"The gist of the issue is that DEA established a new drug code for marihuana extracts as a means to more accurately reflect the activities of scientific research and provide more consistent adherence to the requirements of the Single Convention. We have not changed any control status with this Federal Register Notice. Everything remains schedule I, so no other provisions of the law (registration, security requirements, research protocols, etc.) change. Companies will simple [sic] use a new code for extracts." The Cannabist, December 15, 2016: "New DEA rule on extracts, CBD causes commotion in cannabis industry" by Alicia Wallace.

The DEA contends that the DEA Rule, which was initially proposed in 2011, does not substantively alter anything other than administrative reporting requirements involving the sub-classification of already scheduled compounds. The DEA contends that the DEA Rule does not function to re-classify any drugs. In fact, the DEA has always contended that CBD is a Schedule I drug under the CSA. Fortunately, this is demonstrably inaccurate and the DEA's position can be reconciled with the lawful status of CBD under the conditions described in a-f, above. In its non-binding policy position entitled "Statement of Principles on Industrial Hemp", issued jointly with the Office of the Secretary, US Department of Agriculture and the Food and Drug Administration on August 12, 2016, the DEA acknowledged that industrial hemp produced under the Farm Bill is legal notwithstanding the CSA. Specifically, the DEA stated:

⁹ The DEA asserts that the sub-classification was necessary in order for the USA to comply with the terms of two international treaties regarding illicit drugs, the Single Convention on Narcotic Drugs (1961) and the Convention on Psychotropic Substances (1971).

¹⁰ See http://www.dea.gov/divisions/hq/2015/hq122315.shtml in which the DEA contends that "CBD is a Schedule I controlled substance as defined under the CSA." DEA Headquarter News, December 23, 2015.

"Section 7606 of the Agricultural Act of 2014 legalized the growing and cultivating of industrial hemp for research purposes in States where such growth and cultivation is legal under State law, notwithstanding existing Federal statutes that would otherwise criminalize such conduct." (emphasis added)

Thus, it is the position of the DEA that industrial hemp grown under the Farm Bill (which necessarily includes its constituent parts such as fibers, cannabinoids, and other naturally occurring components and compounds) is legal notwithstanding its Schedule I status. Presumably, the DEA felt no need to address CBD and other cannabinoids derived from the industrial hemp plant since they are unambiguously legal under the Farm Bill and not scheduled in the CSA. In fact, as discussed above, the DEA in a later clarification specifically stated that products, which includes CBD and other unscheduled cannabinoids and terpenes, derived from the excepted parts of the cannabis plant are lawful. By implication, such products are lawful if they come from a lawful plant such as industrial hemp cultivated pursuant to the Farm Bill.

Admittedly, the DEA Rule appears on its face to make illegal that which is legal and its clarification did not go far enough. For these reasons it is the subject of a lawsuit before the 9th Circuit Court of Appeals filed on January 13, 2017. Hemp Industries Association, et al v. USDEA, et al, 17-70162. However, even if the DEA had not published a joint policy position on industrial hemp, it is clear that the DEA Rule does not impact lawfully sourced CBD. This is because the DEA lacks authority to make illegal that which Congress has expressly made legal. In the present situation the DEA Rule directly clashes with at least two Federal statutes: the CSA and the Farm Bill. To the extent that the DEA Rule purports to extend the reach of CSA and/or limit the reach of the Farm Bill the DEA has exceeded its rulemaking authority. This is because the DEA is part of the executive branch of the Federal government, which is charged by Article II of the US Constitution with carrying out and enforcing Federal laws. Although it has the authority to enact rules to carry out its Constitutional obligations, the Executive Branch (which includes the DOJ and the DEA) does not have the authority to enact Federal statutes. If a rule promulgated by the Executive Branch clashes with a Congressionally enacted statute, including by extending its reach or by limiting its scope, the rule violates the Constitution and is void.

This scenario has occurred before. On October 9, 2001 the DEA enacted rules that, when taken together, prohibited importing and distributing sterilized hemp seed, oil, and cake derived from hemp seed, and manufacturing and selling food and cosmetic prod-

ucts made from hemp seed and oil, even if they contained only non-psychoactive trace amounts of tetrahydrocannabinols ("THC"). The DEA's rule stated that "any product that contains any amount of THC is a schedule I controlled substance" Interpretation of Listing of THC in Schedule I, 66 Fed. Reg. 51530, 51533 (Oct. 9, 2001) This rule would have banned the possession and sale of imported hemp products that contained only trace amounts of THC. In a set of companion cases, *Hemp Indus. Ass'n v. DEA*, 357 F. 3d 1012 (9th Cir. Cal. 2004) and *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082 (9th Cir. 2003) (previously referred to, above, as "*Hemp Indus*.") the Court found that the DEA had exceeded its authority and struck down the rules as void. Because of its similarity to the present situation the Court's holding is worth quoting in full:

"The DEA's definition of "THC" contravenes the unambiguously expressed intent of Congress in the CSA and cannot be upheld. DEA-205F and DEA-206F are thus scheduling actions that would place non-psychoactive hemp in Schedule I for the first time. In promulgating the Final Rules, the DEA did not follow the procedures in §§ 811(a) and 812(b) of the CSA required for scheduling. The amendments to 21 C.F.R. § 1308.11(d)(27) that make THC applicable to all parts of the Cannabis plant are therefore void. We grant Appellants' petition and permanently enjoin enforcement of the Final Rules with respect to non-psychoactive hemp or products containing it."

Hemp Indus. expressly clarified that non-psychoactive hemp which contains only trace amounts of naturally occurring THC is not a Schedule I controlled substance. At the time, hemp could not be grown in the USA due to the fact that, among other things, the excepted "mature stalks" of the plant arise after the stalks go through an "immature" phase which was not excepted from the CSA. Thus, until the Farm Bill was enacted in 2014, all lawful hemp had to be imported.

Thus, there are at least three scenarios in which CBD is expressly lawful: (1) Under the CSA when it is sourced from an excepted part of the plant, (2) Under the Farm Bill when it is sourced from an industrial hemp plant cultivated pursuant to a state's hemp laws enacted in accordance with section 7606 of the Farm Bill, and (3) Under *Hemp Indus*.

when it is sourced from a non-psychoactive hemp plant from outside the USA.¹¹ It is my legal opinion that the DEA Rule is properly reconciled with the lawful sourcing of CBD by virtue of the unambiguous language excepting certain parts of the cannabis plant from Schedule I, the Federal statute authorizing industrial hemp cultivation pursuant to the Farm Bill and the subsequent policy position and clarification regarding hemp taken by the DEA, and the holding in *Hemp Indus*. However, even if the DEA were to expressly contend that all CBD is illegal it is clear that the DEA Rule is void, at least to the extent that it encroaches on the aforementioned Federal laws and court holdings. Moreover, the DEA may not prohibit the transportation, processing, sale or use of CBD lawfully sourced pursuant to the Farm Bill due to the Congressional funding restrictions discussed above.

h. The sale of CBD is not banned by the Food and Drug Administration so long as it is not marketed for "use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and is not added to ingestible products.

Medical claims cannot be made about CBD products, nor can they be marketed as dietary supplements. The Food and Drug Administration ("FDA") is responsible for protecting public health in the USA by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, the food supply, cosmetics, and products that emit radiation. (http://www.fda.gov/AboutFDA/WhatWeDo/) On February 4, 2016 the FDA sent official Warning Letters to several retailers of CBD products. All of the letters were similar and later published on the FDA's website. (http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm484979.htm) The thrust of the letters was that the claims made by the retailers established that "that the products are drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act ("the FDA Act") [21 U.S.C. § 321(g)(1)(B)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." Additionally, the FDA claimed that the retailers were illegally marketing their products as "dietary supplements" because CBD products are excluded from the definition of dietary supplement under section 201(ff)(3)(B)(ii) of the FDA Act [21 U.S.C. § 321(ff)(3)(B)(ii)]. The FDA asserted that if an article, such as CBD, has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of

¹¹ Given that hemp is now lawful to grow in the USA pursuant to the Farm Bill, *Hemp Indus*. arguably applies to lawful non-psychoactive hemp cultivated within the USA, in addition to hemp cultivated abroad. I am unaware of any Court decision ruling on this particular issue and so am addressing it in a footnote; however, from a logical standpoint there is nothing in *Hemp Indus*. limiting its scope to foreign sourced hemp.

such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. The FDA contends that substantial clinical investigations have been made public by virtue of GW Pharmaceuticals' investigations regarding Sativex and Epidiolex. Although there are credible claims that CBD was being used as a dietary supplement prior to the initiation of the clinical investigations, claims which if true would make them "grandfathered" in and allowable as dietary supplements, the FDA's position is currently firm on the matter. For the specific purpose of this opinion letter, the FDA's position is taken as correct. It may be that CBD is ultimately accepted as a dietary supplement by the FDA. Until such time, it would be irresponsible of me to recommend marketing CBD products as such.

Additionally, in the summer of 2016, the FDA took the position that adding CBD to ingestible products violates the FDA Act. (http://www.fda.gov/NewsEvents/PublicHealth-Focus/ucm421168.htm#dietsuppsexclude) Specifically, the FDA stated: "Under section 301(II) of the FD&C Act, it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public [It] is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which cannabidiol has been added." Although this appears to be a significant restriction it actually only pertains to the CBD compound itself, and not to naturally occurring formulations, such as CBD rich hemp oil. Fortunately, the FDA's language is very specific and limited. The FDA contends that CBD is a drug. Hemp oil containing naturally occurring CBD is not a "drug." An analogy can be drawn to red rice yeast ("RRY"), a product that contains monacolin K, also known as the cholesterol reducing drug "Lovastatin." Red Rice yeast can be legally sold as long as it is fermented in the traditional manner; however, it cannot be marketed and sold for its monacolin K or specific statin content. Similarly, CBD cannot be extracted, infused in an edible product, and then promoted and sold for its specific CBD content; however, it is legal to do those things with hemp oil.12

Based on the current state of the law, CBD products do not violate the FDA Act so long as they do not make medical claims and/or are marketed as dietary supplements and so long as CBD is not added to edible products. It is my opinion that hemp extracts which

¹² It is important to note that CBD isolate is not illegal to purchase or sell as long as it otherwise complies with the law as set forth herein. It is illegal to add CBD isolate to edible products but not presently illegal to add it to topical cosmetic products. And, as discussed above, it is not illegal to add hemp extract containing naturally occurring CBD to edible products.

contain naturally occurring CBD can be added to edible products but that isolated CBD may not.

PART 2: SISTERS' CBD PRODUCTS MAY BE SOLD, TRANSPORTED, AND POSSESSED IN THE USA

My understanding of Sisters' CBD products is that they are composed of CBD derived from industrial hemp plants lawfully cultivated in California, Oregon, and Colorado pursuant to these States' respective industrial hemp laws, all of which are compliant with the Farm Bill. Accordingly, they are legal throughout the United States at the Federal level for the reasons discussed above: the CBD is sourced from a lawfully cultivated plant and is therefore legal within the State of cultivation and Federal Funds cannot be used to prohibit the transportation, processing, sale, or use of the Company's products. Additionally, Sisters does not intend to market its CBD products as dietary supplements or to make medical claims about them and they are therefore compliant with the FDA Act. At the State level, the Company's products are lawful in states that have enacted industrial hemp laws, in states that receive Federal funds which are used for drug interdiction programs, and states that have epacted medical marijuana laws.

Sincerely,

D. Rodney Kight, Jr., Attorney at Law