April 23, 2018

Submitted Electronically
via www.regulations.gov

Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2018-N-1072 – FDA Request for Comments on "International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol (THC); Stereoisomers of THC; Cannabidiol"

Dear Sir or Madam:

The law firm of Brownson • Norby, PLLC submits this letter in response to FDA's April 9, 2018 Request for Comments "concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of five drug substances." We appreciate the opportunity to provide this comment to FDA and we are hopeful that it will inform FDA's preparation of its response to the World Health Organization (WHO) regarding the relative safety and efficacy of cannabidiol ("CBD") for medical, therapeutic and other uses.

Background

Our law firm assists clients in complying with regulations and laws applicable to CBD. Given the disparate positions of various authorities concerning the status of cannabis-derived substances (i.e. hemp-derived CBD and marijuana), some of our clients have encountered challenges in ensuring that their businesses operate in accordance with all applicable laws and regulations. In particular, clients are concerned about the lack of clarity and consistency in the treatment of CBD within the federal system.

For the reasons set forth below, there should be no doubt that CBD is not and should not be considered a Schedule I substance under international or federal standards, and FDA has a timely opportunity to clarify its policy on CBD when FDA submits its response to the WHO Expert Committee on Drug Dependence ("ECDD").

The stigma surrounding cannabis in general is dissipating with each new development in scientific and medical cannabis research. As scientific and medical communities continue to uncover the potential for medical and therapeutic applications of cannabis, it is essential that

governmental authorities keep in stride. This begins with reevaluating CBD. In light of information learned through scientific research and clinical studies, numerous states have enacted legislation relating to CBD in the past several years. Given the upcoming meeting of ECDD to address pre-reviews of cannabis and cannabis-related substances, FDA has an excellent opportunity to bring federal policy into the modern age.

CBD is Not, Nor Should it Be Considered a Schedule I Substance Under International or Federal Standards

CBD does not fit the definition of a Schedule I substance under the international standard established in the 1961 Convention on Narcotic Drugs ("International Convention"), nor does it fall within the specifications outlined in the 1970 Controlled Substances Act ("CSA"). As such, there is no basis for assigning CBD Schedule I status.

Under both the International Convention and the CSA, substances are scheduled, in part, according to their potential for abuse and adverse effects.[1,2] The International Convention has designated cannabis, cannabis resin, cannabis extracts, and tinctures of cannabis as Schedule I substances, along with substances like morphine, fentanyl, hydrocodone, opium, and cocaine. *See* n.1. Similarly, under the CSA, marijuana ("*Cannabis sativa L.*") is presently a Schedule I substance, along with heroin, LSD, ecstasy and peyote. *See* n.2 (Schedule I substances are described as those "drugs with no currently accepted medical use and a high potential for abuse."). Presently, CBD is not specifically identified as a scheduled substance under the International Convention or the CSA, nor should it be given its potential for medical uses and its noted lack of potential for abuse.[3].

WHO's recent pre-review concluding that CBD poses no potential for abuse or dependency, paired with years of scientific and medical research and studies demonstrate CBD's potential in both medical and therapeutic applications. *See* n.3. Furthermore, on April 19, 2018, an FDA panel concluded that "CBD has a negligible abuse potential" and further shows potential for "the treatment of seizures[.]"[4] Consequently, and in light of the upcoming ECDD meeting, this is an opportune time to establish that CBD is not, nor should it be, a scheduled substance.

CBD is Not a Prohibited Substance Under International or Federal Standards

CBD is not sourced from prohibited elements of the cannabis plant, but instead is derived from "excepted" constituent parts. International and federal standards define illegal marijuana and/or cannabis based on its constituent parts. Under the Convention "cannabis" is defined as "the flowering or fruiting tops of the cannabis plant (resin not extracted)."[5] Under federal law,

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[1] WHO - "Cannabidiol" ; *see also* 1961 Convention (if WHO determines that a substance is not liable to abuse and cannot product ill effects it may reschedule the substance or delete the substance from a schedule).
[2] https://www.dea.gov/druginfo/ds.shtml
[3] 2017 WHO Report on CBD
[4] https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM604736.pdf
[5] http://www.incb.org/documents/Narcotic-Drugs/Yellow_List/56th_Edition/YL_56_edition_EN.pdf

"marihuana" includes all parts of the *Cannabis sativa L.* plant, except

> [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 U.S.C. § 802(16).

Because CBD is derived from the mature stalks of the *Cannabis sativa L.* plant, it does not fit either definition of an illegally sourced substance. Despite these inarguable facts, DEA issued a statement in December 2016 that it considered CBD to fall within the definition of "marihuana" and therefore was an illegal Schedule I controlled substance.[6] DEA's position regarding CBD is currently being challenged in the Ninth Circuit. *See Hemp Indust. Ass'n v. DEA*, No. 17-70162.

A few months later, in light of this glaring contradiction with the statutory definition of "marihuana", DEA walked back its position and stated that "[i]f a product consisted solely of parts of the cannabis plant excluded from the CSA definition of marijuana," such as mature stalks of the cannabis plant "such product would not be included in the new drug code (7350) or in the drug code for marijuana (7360)."[7]

This inconsistency within the federal system is causing some uncertainty for industry stakeholders at a time when FDA should be supporting, not impeding development in this important area. The simple facts are that: 1) CBD is not sourced from prohibited elements of the cannabis plant, 2) CBD lacks the potential for abuse, and 3) CBD has potential medical applications. For these reasons FDA should make a clear policy statement that there is no reason for the scheduling of CBD under international or United States federal law.

CBD is Easily Distinguishable from Marijuana because it Lacks a Psychoactive Component

To further clarify that CBD is distinct from marijuana, even though both substances are derived from the same species (*Cannabis sativa L.*), it is important to examine the function and effects of the substances.[8] Understanding these distinctions should help to resolve any lingering misgivings or stigma surrounding CBD.

As a threshold matter, CBD is typically derived from the hemp plant, which, while in the *Cannabis sativa L.* family, is distinguishable from marijuana based on its THC content. *Compare* Section 7606 of the Agricultural Act of 2014 ("Farm Bill") *with* DEA Drug Fact Sheet – Marijuana. CBD can also be derived from other constituent parts of the cannabis plant, like the mature stalks, which similarly contain little to no THC. As a result of the difference between the sources, CBD lacks cognizable amounts of THC (the psychoactive cannabinoid) and does not

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[6] DEA-342 (Dec. 12, 2016) however, DEA noted: "if it were possible to produce from the cannabis plant an extract that contained only CBD and no other cannabinoids, such an extract would fall within the new drug code 7350."
[7] https://www.deadiversion.usdoj.gov/schedules/marijuana/m_extract_7350.html
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3736954/ ("Cannabis is a complex plant, with major compounds such as [THC] and [CBD], which have opposing effects.")

cause a "high". *See* n.3 ("CBD does not produce the effects that are typically seen with cannabinoids such as THC.") This is why CBD must be viewed distinctly under the law.

DEA's discussion of marijuana centers around the psychoactive effects, the "high", caused by the THC cannabinoid.[9] According to DEA, the perceived dangers of marijuana use arise from the psychoactive effects of THC, which can impact "perception and coordination" and can pose safety risks. *Id*. CBD presents no such similar risk because it lacks a psychoactive component. Because the vast majority of non-medical use CBD products on the market are hemp-derived, they contain less than .3% THC if not 0% THC content.[10] Under the Farm Bill, which creates an exception to the otherwise Schedule I categorization of cannabis, industrial hemp may be legally grown and cultivated so long as it does not have a THC concentration of more than .3% on a dry weight basis. *See* Farm Bill at subp. 2. Consequently, CBD products made from legal hemp also contain .3% or less THC. [11]

Accordingly, the intrinsic differences between CBD and marijuana call for distinct analysis regarding their efficacy in medical and therapeutic applications, and in considering their ultimate legal status. Because CBD does not pose the risks DEA associates with marijuana and THC, and because CBD is derived from hemp, there is no basis for considering it a prohibited substance.

WHO Reports No Public Health Risks or Abuse Potential for CBD

Following a meeting in November of 2017, "the WHO Expert Committee on Drug Dependence (ECDD) concluded that, in its pure state, **cannabidiol does not appear to have abuse potential or cause harm**." *See* n.3 (emphasis added).

The pre-review report that followed further recognized the applicability of CBD as a medical treatment for epilepsy—a function for which FDA is currently reviewing the substance in relation to a new drug application. *See id*; *see also* n.4. WHO further noted that "there is no evidence of recreational use of CBD or any public health related problems associated with the use of pure CBD." Ultimately, WHO concluded that

> CBD is not currently a scheduled substance in its own right (only as a component of cannabis extracts), [and] **current information does not justify a change in this scheduling position and does not justify scheduling of the substance**.

Id. (emphasis added).

There is no new information or studies that alter this result, and the ECDD's determination is

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[9] DEA Drug Fact Sheet – Marijuana

[10] Medical-use only CBD products derived from marijuana contain higher levels of THC, and are subject to stringent state law restrictions and are only available to qualifying patients through state sanctioned providers.

[11] CBD as discussed herein refers to the naturally occurring cannabinoid derived from cannabis, ***not*** synthetic compounds that are not CBD and do have adverse results. *See* Article on Synthetic CBD Oils; *see also* Army Public Health Alert on Synthetic CBD. This is also the case with synthetic marijuana, such as K2, which has also recently been in the news. *See* Article on Synthetic Marijuana. These are unrelated to naturally occurring CBD and THC and consist of "a mixture of hundreds of chemicals". *Id.*

instructive not only for the purposes of informing FDA's response, but also for the purposes of informing the United States government's consideration of CBD.

WHO and State Government Recognition of CBD's Therapeutic Applications

In the past several years, CBD's potential for medical, therapeutic, and other applications has been recognized by numerous state legislatures. *See e.g.* Alabama, Arkansas, Delaware, Florida, Georgia, Iowa, Kentucky, Mississippi, Missouri, Nebraska, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, Wyoming. The laws vary as to the permissible THC content and the requisite medical diagnosis to qualify under the law, but what they do have in common is the recognition of the value CBD has in mitigating symptoms of debilitating conditions like epilepsy, Tourette's, Crohn's, intractable pain, and various terminal illnesses. *See e.g.* Arkansas, Florida's "Charlotte's Web Bill", Georgia's "Haleigh's Hope Act"; *see also* n.3 at Table 1"Overview of disease for which CBD may have therapeutic benefits" (listing Alzheimer's, Parkinson's, MS, Huntington's, psychosis, anxiety, depression, cancer, nausea, arthritis, infection, IBS, cardiovascular diseases, diabetic complications.) In addition to the medical-use only states, other states like Indiana, have laws explicitly legalizing CBD generally, thereby permitting the purchase and use of CBD for various other applications such as muscle soreness, nausea, stress, insomnia, and headaches.

It is anticipated that FDA's own review of CBD through the new drug applications for products incorporating the substance will further inform the federal government that the product has significant benefits and presents little to no risk of abuse or dependence. Until that time when FDA has completed its review, much can be learned from the studies and trials already conducted, which prompted state legislatures and WHO to conclude that CBD's value far outweighs any potential harm.

Conclusion

As FDA prepares its submission to WHO, it is critical to reflect on the wealth of credible studies and research by respected authorities (including WHO) concluding that CBD presents a strong potential for therapeutic applications—and, perhaps just as importantly—shows no potential for abuse or dependency. For these reasons, CBD should not be scheduled as a Schedule I substance under United States federal law or under international control.

We appreciate the opportunity to participate in this discussion.

Respectfully,

/s/ Lindsey A. Streicher

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