KOUSSEVITZKY LAW
LET'S GROW YOUR BUSINESS

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Miracle Nutritional Products
4004 Shoal Line Blvd
Spring Hill, FL 34607

Re: Legal Opinion Letter to Mr. David Zeuner

Dear Mr. Zeuner,

As you requested, my law firm has researched the current legal status of industrial hemp and hemp derived products containing CBD. The purpose of this opinion letter is to provide you with information about the recent passage of the 2018 Farm Bill, where FDA regulations are likely to come into play, what guidelines Miracle Nutritional Products ("MNP") should heed to when marketing and branding their products, and some best practices for building consumer trust in an industry whose regulations continue to evolve. By way of background, CBD is short for cannabidiol, a compound found in both cannabis and hemp plants. Hemp and cannabis are the same plant, but hemp is bred to have very low levels of THC (delta-9-tetrahydrocannabinol, the intoxicating compound in cannabis). The laws governing CBD are federal, state, and local, and involve both statutory law and complex regulations. Hemp is different and distinguished by its use and chemical makeup, and has long been cultivated for non-drug use in the production of food, industrial items, and other goods.

Fortunately, with the recent passage of the 2018 Farm Bill (Agriculture Improvement Act), more clarity exists than ever before as it pertains to hemp and hemp derived CBD products. Under the 2014 Farm Bill, Congress specifically permitted the growth, cultivation and study of industrial hemp solely under agricultural pilot programs authorized by state law. [1] The 2018 Farm Bill, which passed on December 20, 2018, declares that interstate commerce of hemp products is permitted. [2] The bill also covers subject matters such as agricultural subsidies, commodity support, and organic certification requirements. Tremendously important for operators such as MNP, the bill also enables banks, payment processors and credit card companies to service the

[1] Federal Agricultural Act of 2014, P.L. No. 113-79
[2] H.R. 2 (115th): Agriculture Improvement Act of 2018

hemp industry, as well as insurance companies to service cultivators with a variety of crop insurance options. Within the bills 500 pages, the provisions relating to Hemp are the ones that provide clarity to the CBD industry, which has been operating in legal confusion prior to the passage of the law.

Most notably for Miracle Nutritional Products and all other CBD companies is that the bill removes hemp (defined as *Cannabis sativa L.* and any part of that plant containing less than 0.3% THC) from the Controlled Substances Act, meaning that to cultivate or sell hemp is no longer a federal crime. Thus, CBD and Hemp companies no longer need fear enforcement on a federal level from both the Drug Enforcement Agency and Department of Justice based on hemps prior classification as a controlled substance.

Additionally, and equally for CBD businesses, the Act specifically allows for interstate commerce of hemp or hemp products. This is huge news for CBD companies and should provide confidence to CBD operators and investors and operators going forward. Prior to the new legislation, industrial hemp was required to be cultivated and processed for research purposes at accredited universities. The 2018 Farm Bill makes clear that hemp can be sold commercially.

The Farm Bill is a historic milestone. From a legal perspective, CBD brands can operate with much more confidence since the passing of the Farm Bill last year which clarified that interstate commerce of hemp products is permitted under Federal Law. However, we are still awaiting regulations that will provide guidance to CBD companies on best operating practices and more transparency for CBD consumers and patients.

Shortly after The Farm Bill was signed into law, the Food and Drug Administration released a statement reminding the public and CBD businesses that they still have the authority to regulate hemp consumer products that fall within their purview.[3] Specifically, the FDA regulates food, drugs, biologics, medical devices, electronic products that give off radiation, veterinary products, and tobacco products. As we await potential regulations from the FDA regarding CBD, companies should continue to ensure that the companies labeling is not misleading consumers. Fortunately, Miracle Nutritional Products already independently seeks and obtains third party testing that verifies the contents of what's inside of an MNP product. This is information can be accessed via QR Code made plainly visible on MNP products. (*see photo below)*

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

By independently obtaining a Certificate of Analysis and providing this to your customers, MNP will continue to be ahead of the regulatory curve and at the same time build consumer trust. Many states may already require third party testing for licensed hemp cultivators, but even if it doesn't, and if it is feasible for a business to do so, the practice helps generate customer loyalty as you build your brand and will pave the way for complying with future CBD regulations once they are introduced. We are hopeful that the FDA will address ambiguities in the near future.

The success of CBD products has demonstrated to Congress that hemp is a valuable agricultural commodity, and hopefully soon the FDA will provide bright-line guidance regarding CBD products. The FDA's December announcement made clear that if you are making claims of a therapeutic benefit, or any other disease claim, you must first have FDA approval for the product's intended use before introducing the product into interstate commerce. Therapeutic claims are those that market their products to suggest they are *intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases*. There is not a bright line test to determine whether a therapeutic claim is made, and more than 10 distinct criteria are used to determine whether a claim is therapeutic.

Some claims relating to efficacy or mechanism of operation are permitted without prior FDA approval -- these claims are called structure/function claims. These statements describe the effect a dietary supplement may have on the structure or function of the body. Structure/Function Claims are appropriate and do not require FDA approval before marketing the product. Whether a claim is a permitted Structure/Function statement or a Therapeutic Claim requires a ten factor analysis and the determination is made based on the totality of the product's marketing and branding.

The FDA takes into account many factors including not only whether the signs are characteristic of non-disease states, but also the name of the product (and whether it contains a reference to a disease); whether there is an effect on a natural state or process; has a role in the body's response to disease, and others. A complex, multifactor analysis of the product's entire marketing copy and brand identity is required to make a concrete determination, but this example is a good starting point for developing an understanding of what constitutes a therapeutic claim. As the hemp-derived CBD category continues to mature, responsible manufacturers such as MNP must continue to take the lead and demonstrate how to safely produce and sell CBD products.

In addition to Federal Law, CBD operators must comply with State Law, which varies greatly across the U.S. Individual states can and have placed specific controls on hemp and hemp-derived products. Misinformation regarding the legality of hemp-derived CBD products continues to circulate, much due to the confusing nature of current law enforcement agency policies and priorities which can make it impossible to predict with absolute certainty how local, state, or federal law enforcement officials will treat industrial hemp and derivative products, particularly CBD.

Participating in self-regulatory initiatives such as the U.S. Hemp Authority Certification Program help CBD companies such as MNP improve self-regulation as well as educate and inspire the future regulations that will eventually act as the framework for quality control on a State and Federal Level. As States begin to develop their own regulatory schemes, programs such as The U.S. Hemp Authority Certification Program are providing guidance for best practices and third-party audits to certify growers and processors of hemp products.

The Congress enacted 2018 Farm Bill is landmark legislation broadly authorizing hemp, a commonly used term for non-psychoactive, non-drug varieties of the species *Cannabis sativa L.* when cultivated for industrial or food uses, rather than drug purposes. More than 30 nations grow hemp as an agricultural commodity, which is sold on the world market. Hemp and derived CBD products will be one the most watched item of 2019. All eyes will be on regulators and operators as the market continues to grow and mature over the coming years. Koussevitzky Law urges you not to assume as fact any across-the-board claims about the legality or illegality of hemp and CBD products, particularly those made in a self-serving commercial setting. If you have any specific questions, please do not hesitate to contact me or my office.

Sincerely,

Andrew Koussevitzky, Esq.
Attorney at Law