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December 31, 2018

What Does the 2018 Farm Bill Mean for the Hemp and CBD Businesses?

President Trump signed the Agriculture Improvement Act of 2018 (popularly known as the 2018 Farm Bill) into law on December 20, 2018. Among the 2018 Farm Bill's broad-ranging provisions, it legalizes the cultivation and sale of hemp at the federal level, effective January 1, 2019.[1] This will have important ramifications not only for the hemp industry in the United States, but also for business involving cannabidiol (CBD).

### **How Federal Law Regarding Hemp and CBD Has Evolved**

Even before the 2018 Farm Bill went into effect, hemp and CBD have long presented unique opportunities for business growth in the United States. Hemp is a fast-growing, easily-cultivated variety of the *Cannabis sativa* L. plant with many commercial uses, such as textile products and food. Marijuana is a different variety of the *Cannabis sativa* L. plant and contains high concentrations of tetrahydrocannabinol (THC), the chemical that produces psychoactive effects. In contrast, hemp by definition contains minimal concentrations of THC. CBD is a different compound derived from the *Cannabis sativa* L. plant (either marijuana or hemp varieties) with numerous putative health and general wellness benefits.

Despite the fact that neither hemp nor hemp-derived CBD contain significant amounts of THC, until December 20, 2018, hemp was categorized as a Schedule I substance under the Controlled Substances Act, the main federal criminal law regarding prohibited drugs, alongside narcotics such as heroin. As such, it was generally illegal at the federal level to cultivate, possess or distribute the hemp plant or CBD derived from the hemp plant, although certain inert portions of the *Cannabis sativa* L. plant (hemp or marijuana), such as the stalks or non-germinating seeds, could be bought or sold.

Moreover, federal regulations enforced by the Drug Enforcement Agency (DEA), the lead agency responsible for federal criminal drug enforcement, forbade products intended for human consumption that contain any portion of the cannabis plant, including the inert portions otherwise exempted from the Controlled Substances Act. *See* 21 C.F.R. § 1308.35. This effectively made CBD products, regardless of how derived, illegal at the federal level.

Nevertheless, hemp and CBD businesses have thrived in numerous state jurisdictions in which such products are legal. These businesses have operated in a quasi-legal status under U.S. Department of Justice policy, which has effectively permitted otherwise legitimate industry related to cannabis to operate in state jurisdictions where such business is legal and well-regulated.

Regulations enforced by the Food and Drug Administration (FDA) present additional, non-criminal legal concerns for the sale of hemp-derived CBD products. Some manufacturers and marketers of CBD-infused products—including food, beverages, dietary supplements and creams—claim that the products are effective in the treatment and prevention of various diseases. The FDA has taken the position that such claims subject the products to regulation as drugs, which typically requires prior approval from the FDA based upon clinical trials to establish product safety and efficacy. The FDA has issued a number of warning letters over the past three years to halt the marketing of products for which such claims are made, although no enforcement actions have followed.

There are two other concerns arising from FDA regulation. First, in June 2018 the FDA approved a prescription drug for the treatment of seizure disorders that contains CBD as the active ingredient. Under federal law, a food may not include an approved drug, such as CBD, without further FDA approval. Second, as a new ingredient in food, it is important that the safety of CBD for human consumption be established before a food product containing it may be put on the market.

## **The 2018 Farm Bill**

On December 12, 2018, Congress passed the [2018 Farm Bill](#), which was signed into law by President Trump the following week. Importantly, the bill includes key text regarding hemp that was championed by Senate Majority Leader Senator Mitch McConnell (R-KY) with strong bi-partisan backing:

- The 2018 Farm Bill defines hemp as the plant *Cannabis sativa* L. and any part of the plant with a delta-9 THC concentration of not more than 0.3 percent by dry weight. This definition is consistent with the definition of "industrial hemp" in the 2014 version bill, which created a limited agricultural pilot program regarding research into industrial hemp.
- The 2018 Farm Bill removes hemp from the Controlled Substances Act, paving the way for the wholly legal cultivation, possession, sale and distribution of the hemp plant.
- The 2018 Farm Bill delegates to states and Indian tribes the broad authority to regulate and limit the production and sale of hemp and hemp products within their borders. States and Indian tribes cannot, however, limit the transportation or shipment of hemp and hemp products through their respective jurisdictions.

## **Consequences of the 2018 Farm Bill to the Hemp and CBD Industries**

In 2017, U.S. retail sales for products containing hemp, including food and beverage products, personal care products, household products, and supplements, reached \$820 million. Based on current demand, forecasters project hemp and CBD to be a \$1 billion industry by 2020. This year's passage of the 2018 Farm Bill will certainly boost hemp and CBD production and sales.

Federal legalization means that hemp producers and businesses that deal in hemp and hemp-derived products, such as CBD, are now free to pursue their businesses more aggressively, and with less concern that a seismic shift in enforcement priorities could result in their investigation or prosecution by federal authorities. Following passage of the 2018 Farm Bill, CBD producers, in particular, will have much greater incentive to use hemp as their primary source for CBD (rather than marijuana). It is still important, however, that businesses involved in the hemp industry comply with state and federal regulations regarding legalized hemp, and that businesses selling CBD (including food and beverages) stay clear of the aggressive health-related marketing that may result in unwanted attention from the FDA and carefully navigate the other health and food regulatory issues implicated by FDA oversight.

## **ENDNOTES**

[1] Text - H.R.2 - 115th Congress (2017-2018): Agriculture Improvement Act of 2018, Congress.gov (2018)

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