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Florida Approves Plan for Hemp Production, Despite FDA Constraints on CBD

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Florida is a step closer to permitting hemp production, with Florida Governor Ron DeSantis signing into law legislation set forth in Florida Statutes Section 581.217, establishing a state hemp program within the Florida Department of Agriculture and Consumer Services (FDACS). The law tasks the FDACS with developing regulations for administering the state's hemp program, including regulations for licensing, cultivation, and distribution of hemp and its constituent parts, which include cannabidiol (CBD), and submitting the state's plan to the United States Secretary of Agriculture for approval. The law took effect July 1, 2019.

Florida's new state hemp plan comes on the heels – and as a direct result – of passage of the Federal Agricultural Improvement Act of 2018, signed into law by President Trump on December 22, 2018. Commonly referred to as the Farm Bill, the legislation took important steps to remove a number of federal prohibitions that had stymied the U.S. hemp industry for decades. For example, the Farm Bill expanded the definition of hemp to include any part or derivative of the cannabis plant with 0.3 percent or less THC; removed most forms of hemp from the Controlled Substances Act; tasked the United States Department of Agriculture (USDA) with establishing benchmark federal regulations governing the licensing, cultivation, and distribution of hemp; and, importantly, permits the states to submit state-sponsored hemp programs to the USDA and apply for primary regulatory authority over the production of hemp in their jurisdictions.

Florida's newly enacted hemp program therefore constitutes the state's plan for regulation of hemp and its derivative products as contemplated by the Farm Bill. The new law mandates that the FDACS – within 30 days of the USDA's enactment of not-yet-announced federal regulations – submit the state's hemp plan to the U.S. Secretary of Agriculture for approval. Should Florida's hemp plan not be approved by the USDA, the law directs FDACS to develop a recommendation to amend the plan for ultimate approval and re-submission. In addition, the law establishes licensure requirements for growers and a structure to ensure the purity, labeling, and quality compliance of cultivated hemp products for the protection of Florida consumers. The law also establishes a 15-member state advisory council to assist FDACS with development of policies and procedures related to hemp cultivation in the state.

Despite Florida's new hemp law, significant challenges remain for companies and individuals seeking to sell CBD-containing foods and beverages in Florida. The United States Food and Drug Administration (FDA) continues to exercise regulatory authority over the addition of hemp and its derivatives, including CBD, to conventional foods, beverages, dietary supplements, cosmetics and other products introduced in interstate commerce and within the ambit of FDA's jurisdiction. FDA's authority is provided by the federal Food, Drug, and Cosmetic Act (FDCA), which prohibits the adulteration or misbranding of such products. FDA currently takes the position that CBD and other cannabinoids are impermissible additives that cause food and dietary supplements to be adulterated under the FDCA. FDA has been less clear as to whether it views CBD as an acceptable cosmetic ingredient.

After the Farm Bill was signed into law in December of 2018, then-FDA commissioner Scott Gottlieb issued a statement recognizing the enormous public interest in hemp and CBD, but cautioned that, despite passage of the bill, "it's unlawful under the [FDCA] to introduce food containing added CBD or THC into interstate

commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived." Commissioner Gottlieb did, however, conclude that pathways remain available for FDA to consider whether there are circumstances in which certain cannabis-derived compounds, primarily CBD, might be permitted in a food or dietary supplement. Commissioner Gottlieb stated that "[a]lthough such products are generally prohibited to be introduced in interstate commerce, the FDA has authority to issue a regulation allowing the use... in a food or dietary supplement" and that FDA is "taking new steps to evaluate whether [FDA] should pursue such a process."

More recently, on July 12, 2019, FDA Principal Deputy Commissioner Amy Abernathy, M.D., Ph.D., formally announced that FDA plans to expedite the development of regulations specific to CBD, with the intent of issuing a progress report by the end of summer or early Fall 2019. Principal Deputy Commissioner Abernathy's announcement comes on the heels of increased bipartisan pressure from Congress on FDA to act expeditiously in developing sound regulations governing the sale, distribution, and use of CBD at the federal level, particularly with respect to CBD as a food additive and dietary ingredient. To be sure, on June 25, 2019, Senator Ron Wyden issued a letter to the FDA urging the Agency to issue formal guidance announcing a CBD enforcement discretion policy no later than August 1, 2019. Senator Wyden further urged the FDA, pending publication of a permanent final rule, to issue an interim final rule ensuring that a regulatory pathway exists for the lawful use of CBD as a food additive and as a dietary ingredient. Across the aisle, on June 27, 2019, Senate Majority Leader Mitch McConnell met with Acting FDA Commissioner Ned Sharpless and similarly urged him to develop regulations so that hemp-derived CBD can be lawfully marketed in the United States. Following the meeting, Senator McConnell issued a public statement reaffirming that "Congress's intent was clear from the passage of the Farm Bill that these products [CBD foods and dietary ingredients] should be legal, and our farmers, producers and manufacturers need clarity as well as a workable pathway forward regarding the agency's enforcement."

While federal law governing the production, sale, distribution, and use of CBD-containing foods, beverages, and dietary supplements remains in a haze, Florida's hemp plan will hopefully provide clarity at the state level to Florida businesses with respect to the licensing, cultivation, and distribution of hemp as an agricultural commodity and with respect to the sale, distribution, and use of hemp-derived products, in particular to the use of such products not directly intended for use as foods or beverages.

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