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June 12, 2019

FDA Regulation of Cannabidiol (CBD) Products

Cannabidiol (CBD) is promoted as treatment for a range of conditions, including epileptic seizures, post-traumatic stress disorder, anxiety, and inflammation—despite limited scientific evidence to substantiate many of these claims. In the United States, CBD is marketed in food and beverages, dietary supplements, and cosmetics—products that are regulated by the Food and Drug Administration (FDA). CBD is also the active ingredient in an FDA-approved pharmaceutical drug, Epidiolex®. CBD is a plant-derived substance from *Cannabis sativa*, the species of plant that includes both hemp and marijuana, but from different plant varieties or cultivars. CBD is the primary nonpsychoactive compound in cannabis, whereas tetrahydrocannabinol (THC) is cannabis's primary psychoactive compound.

Regulation of CBD Products

Hemp and marijuana have separate definitions in U.S. law and are subject to different statutory and regulatory requirements. Marijuana is a Schedule I controlled substance under the Controlled Substances Act (CSA, 21 U.S.C. §§802 et seq.) and is regulated by the Drug Enforcement Administration (DEA). The unauthorized manufacture, distribution, dispensation, and possession of marijuana is prohibited. Marijuana-derived CBD is illegal at the federal level, with the exception of use as an active ingredient in the FDA-approved drug Epidiolex®. Despite the federal prohibition on growing, selling, or possessing the drug, marijuana-derived CBD that has not been approved by FDA has been made available in states where medical and/or recreational cannabis is legal under state law. In some states, buying CBD may require obtaining a medical cannabis prescription; elsewhere, CBD may be sold only at a licensed dispensary. As a result of recent legislative changes enacted in the 2018 farm bill (Agriculture Improvement Act of 2018, P.L. 115-334), hemp-derived CBD is not subject to regulation and oversight as a controlled substance at the federal level.

Legislative Changes in the 2018 Farm Bill

Legislative changes related to hemp enacted as part of the 2018 farm bill were widely expected to generate additional market opportunities for the U.S. hemp market. The 2018 farm bill removed long-standing federal restrictions on the cultivation of hemp, making it no longer subject to regulation and oversight as a controlled substance by the DEA. Instead, hemp production is now subject to regulation and oversight as an agricultural commodity under the U.S. Department of Agriculture (USDA). The 2018 farm bill also expanded the statutory definition of what constitutes *hemp* to include "all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers," as long as it contains no more than a 0.3% concentration of delta-9 THC (7 U.S.C. §1639o). All other cannabis is considered to be *marijuana* under the CSA and remains regulated by DEA. Some stakeholders expected that these changes would eliminate one obstacle to production and marketing of hemp and hemp-derived compounds, including CBD. However, the farm bill explicitly preserved FDA's authority under the Federal Food, Drug and Cosmetic Act (FFDCA, 21 U.S.C. §§301 et seq.) and Section 351 of the Public Health Service Act (PHSA, 42 U.S.C. §262), including for hemp-derived products. According to FDA, "because the 2018 Farm Bill did not change FDA's authorities, cannabis and cannabis-derived products are subject to the same authorities and requirements as FDA-regulated products containing any other substance, regardless of whether the products fall within the definition of 'hemp' under the 2018 Farm Bill."

FDA Regulation of CBD Products

FDA, under the FFDCA, regulates many of the products marketed as containing cannabis and cannabis-derived compounds, including CBD. Hemp-derived CBD is generally marketed and sold as an ingredient in food or beverages, cosmetics, personal care products, and dietary supplements. Epidiolex® is the first (and only) FDA-approved prescription drug formulation of highly purified, marijuana-derived CBD in the United States.

There are several provisions of the FFDCA that FDA believes restrict the use of CBD in food and dietary supplements. Under the FFDCA, it is a prohibited act to introduce into interstate commerce a food to which has been added an approved drug or a drug for which substantial clinical investigations have been instituted and made public. There are several exceptions to this: (1) if the drug was marketed in food before approval as a drug or before clinical investigations were instituted; (2) if the Secretary has issued a regulation approving the use of such drug in the food; (3) if the use of the drug in the food is to enhance the safety of the food and not to have independent biological or therapeutic effects on humans, and the use is in conformity with specified requirements; or (4) if the drug is a new animal drug whose use is not unsafe (21 U.S.C. §331(ll)). FDA has concluded, based on available evidence, that these exceptions do not apply to CBD. However, according to FDA, cannabis-derived ingredients that do not contain CBD (or THC) may fall outside the scope of the prohibition in §331(ll). More specifically, foods containing parts of the hemp plant that include only trace amounts of CBD (e.g., hemp seed and hemp-seed derived ingredients) may be lawfully marketed under certain circumstances—pursuant to FDA approval as a food additive (by regulation) or a determination that the substance is generally recognized as safe (GRAS). FDA has not approved hemp as a food additive but has evaluated three GRAS notices related to hemp seed-derived ingredients (hulled hemp seeds, hemp seed protein, and hemp seed oil), allowing them to be added to human food under specified conditions.

The FFDCA expressly excludes from the definition of a dietary supplement a substance that is an active ingredient

in an approved drug, or a drug for which substantial clinical investigations have been instituted and made public, unless the substance was marketed as a dietary supplement or food before approval or before clinical investigations were instituted. An exception to this is if FDA promulgates regulations that use of such substance in a dietary supplement is lawful (21 U.S.C. §321(ff)(3)). Because CBD is an active ingredient in an approved drug (i.e., Epidiolex®) and was the subject of clinical investigations before it was marketed in food, FDA has determined that it may not be marketed in or as a dietary supplement.

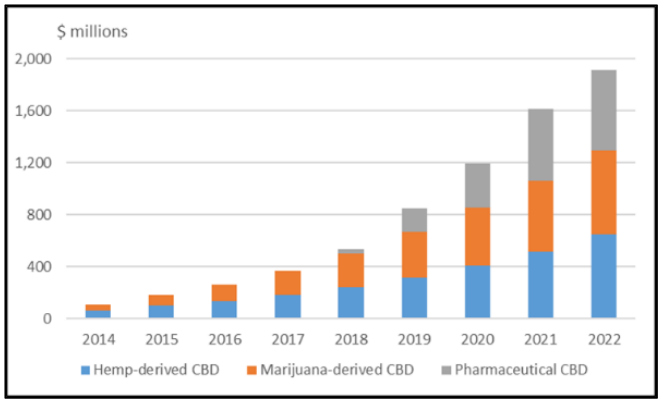
In a December 2018 statement, FDA stated that it is "unlawful under the [FFDCA] to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived." The agency reiterated this view in an April 2019 statement. In addition, since 2015, FDA has issued numerous warning letters to firms marketing CBD products as dietary supplements and making unsubstantiated therapeutic claims. Pursuant to the FFDCA, if a product is accompanied by claims implying that its intended use is the cure, mitigation, treatment, or prevention of a disease, FDA generally considers that product to be a drug and subject to premarket approval. If a company has not obtained approval of a drug prior to marketing, it is in violation of the FFDCA. Thus, for a CBD product to make therapeutic or disease-treating claims, whether hemp-derived or otherwise, it must be approved by FDA for that use. While FDA has issued warning letters to manufacturers of CBD products marketed as dietary supplements for various FFDCA violations, including for making unsubstantiated claims, the agency has not yet taken enforcement action against companies marketing CBD cosmetic products.

Some in Congress have asked FDA to clarify its position regarding hemp-derived products, and FDA has established a working group "to consider whether there are legislative options that might lead to more efficient and appropriate pathways than might be available under current law." Some states and local jurisdictions (e.g., Maine, New York, and California) have decided to disallow the sale of hemp-derived CBD edible products, given concerns that hemp-derived CBD is not an FDA-approved food additive. Law enforcement officials are also highlighting the need for testing and sampling technologies and protocols to more readily distinguish between hemp and marijuana.

CBD Market in the United States

From an industry perspective, there are three markets for CBD: hemp-derived CBD, marijuana-derived CBD (currently a Schedule I controlled substance), and pharmaceutical CBD (currently only Epidiolex®). In 2018, CBD sales in the United States from all three markets were estimated at $534 million, according to the *Hemp Business Journal* (**Figure 1**). More than 1,000 companies produced and marketed CBD for the U.S. market. Compared to 2014, when total CBD sales were a reported $108 million, U.S. sales of CBD have risen fivefold. This same source projects U.S. sales of CBD will exceed $1 billion in 2020 and reach nearly $2 billion in 2022, divided about evenly among the three markets. At the retail level, CBD is marketed in a range of foods and beverages, dietary supplements, and cosmetic and personal care products, some of which are now being sold by large retailers such as CVS Pharmacy and Walgreens.

Figure 1. Total U.S. CBD Sales, by Channel



Source: Hemp Business Journal, *The CBD Report: 2018 Industry Outlook*, 2019 (New Frontier Data). All pharmaceutical channel sales are represented by the drug Epidiolex®.

Considerations for Congress

While the 2018 farm bill removed hemp and its derivatives from the definition of marijuana in the CSA, several obstacles may limit the marketing of hemp and its derivatives, including CBD, particularly in FDA-regulated products. One obstacle is that these products remain subject to the FFDCA, and FDA has determined that it is unlawful to introduce food containing added CBD into interstate commerce, or to market CBD products as, or in, dietary supplements. While FDA can initiate rulemaking to approve the use of CBD in food or to allow its use in dietary supplements, former FDA Commissioner Gottlieb has stated that because rulemaking is often a "long process" and given the complexity of this issue, a legislative fix may be a more efficient option. Congress could, for example, allow for CBD in dietary supplements in specific concentrations. However, one consideration in determining whether a legislative fix is appropriate is the potential for adverse health effects. Dietary supplements are not evaluated by FDA for safety and effectiveness prior to marketing, and clinical trials to support approval of Epidiolex® have demonstrated the potential for liver injury. Questions also remain regarding the therapeutic benefits of CBD; to date, FDA has approved one CBD drug product. Per FDA, "any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug." CBD is marketed in a range of FDA-regulated products, and because there are so many of these products on the market, FDA has focused its enforcement priorities on those companies and products that pose the greatest risk to consumers. Despite continued promotion and sales of CBD—whether hemp- or marijuana-derived—as treatment for a range of conditions, there remains considerable regulatory and legal uncertainty in the U.S. CBD market.

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IF11250