Legal Limbo

The Current State of CBD Regulation and the Manufacturer's Conundrum

By Sarah A. Westby

Cannabidiol (or CBD) products exist in a gray area of U.S. law and regulation. The sale and distribution of CBD derived from the hemp plant is legal under federal law, as long as it contains less than 0.3 percent tetrahydrocannabinol (THC). In addition to lawful domestic production, federal law permits the importation of CBD products. However, the U.S. Food and Drug Administration (FDA) retains jurisdiction over CBD. This means that the FDA can examine, seize, and prevent the sale and distribution of CBD oil and related products that do not comport with FDA regulations.

While there is a movement within the FDA to classify certain CBD products and uses of such products as safe, CBD products continue to exist in legal limbo: the sale and manufacture of CBD is legal under federal law but may violate FDA regulations. As things stand now, the risk of FDA involvement is low if the product is not a food additive, is not marketed as a dietary supplement, and does not make health claims related to treating, preventing, or curing a disease.

Legal Status of CBD Under U.S. Law. The United States legalized the sale and distribution of CBD derived from the hemp plant that contains less than 0.3 percent THC by passage of the Agriculture Improvement Act of 2018, known colloquially as "the Farm Bill." *See* **Agriculture Improvement Act** §10114l. The Farm Bill removed hemp and hemp-derived products such as CBD from the definition of "controlled substances" under the Controlled Substances Act. 21 U.S.C. §802(16). Subsequent regulations issued by the U.S. Department of Agriculture (USDA) make clear that states cannot prevent the transport of CBD across state lines. *See* Interim Final Rule, **Establishment of a Domestic Hemp Production Program**, 84 Fed. Reg. 58,522 (Oct. 31, 2019) (to be codified at 7 C.F.R. pt. 990). Nevertheless, the Farm Bill maintains the FDA's authority to regulate the marketing, distribution, and sale of CBD products.

Legal Requirements for Importing CBD into the United States. The USDA permits the importation of hemp seeds and plants as long as the importer provides certain documentation. While CBD oils and isolates would not fall within the purview of USDA importing regulations, it is possible that a cannabis-derived product, such as CBD, could be refused admission. From an importing perspective, the importer (or broker) may need to declare that the products are FDA regulated on the required paperwork (depending on the labeling and intended use), which could trigger an FDA review to determine if the products comply with the same standards as domestic products. The FDA determines whether products are admissible into U.S. commerce and may refuse entry to any that violate or appear to violate any provisions of the Federal Food, Drug, and Cosmetic Act. CBD manufacturers seeking to import CBD oil or products containing CBD isolate should be prepared to provide certification

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that their product contains less than 0.3 percent THC by dry weight.

FDA Regulation of CBD Products. While the distribution and sale of hemp-derived CBD is legal under the Farm Bill and USDA importing regulations, the FDA's regulation of CBD products remains amorphous. *See* **FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)**, U.S. Food & Drug Admin. (Mar. 11, 2020). As a result, CBD manufacturers, distributors, and retailers lack clear guidance on which products are cleared to sell and which labeling requirements must be met. The FDA anticipates issuing regulations governing the sale and marketing of CBD products in the near future, but in the interim, various public statements and warnings from the FDA provide some insight on avoiding FDA scrutiny.

For instance, the FDA recently expressed concern about the widespread sale and use of CBD products to treat various health conditions. While it is exploring pathways to approve CBD products for sale outside of the drug context, the FDA currently considers certain product formulations and uses of CBD unlawful. First, the FDA has stated that CBD products cannot be sold as food additives or as dietary supplements. *Id*. In addition, the FDA has issued a series of warning letters admonishing CBD companies that claim that their products treat, cure, or prevent diseases, as well as those that market their products with false claims, such as omitting ingredients or making incorrect statements about the amount of CBD that a product contains. *See* Press Release, Stephen M. Hahn, Comm'r, U.S. Food & Drug Admin., Statement, **FDA Advances Work Related to Cannabidiol Products with Focus on Protecting Public Health, Providing Market Clarity (Mar. 5, 2020).**

It is also worth noting that under the Federal Trade Commission Act, it is unlawful to advertise that a product can prevent, treat, or cure human disease unless the advertiser possesses competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time that they are made.

A Final Word of Caution. There is a fine line between an impermissible health claim and a permissible structure/function claim under FDA regulations. Manufacturers and distributors of CBD products must take care not to cross that line and thus wind up on the FDA's enforcement radar. FD