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insights

Cannabis Conflicts Part I: Is it a food, drug or dietary supplement?

In the increasing number of states that have legalized the cultivation, manufacture and sale of medical and recreational cannabis, cannabis companies are looking at three primary avenues to market cannabis-containing products: as food, as dietary supplements, or as a drug.

Some state legislation allows for cannabis-based "edible" products such as cannabis-containing cookies or brownies. Many of these new state laws actually refer to these edible products as food, including Illinois. Yet to date, the Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) have remained relatively silent on these cannabis-based "edible" products. In fact, despite the FDA's unquestioned authority to regulate food and medical products, the agency has yet to change its position that cannabis is a controlled substance.

The intersection of new state legislative schemes and the FDA's position and authority over foods, drugs and dietary supplements creates an inherent conflict between federal and state laws. Businesses selling cannabis products must not only be aware of but also learn to navigate this difficult regulatory "tightrope." Here in Part I of our "Cannabis Conflicts" series, we will discuss the three possible categories of cannabis products, and how state and federal law intersect for each category. In Part II, we will dive into the conflicting food labeling requirements for edible cannabis products.

Cannabis as a food

One option available to cultivators and dispensaries is to treat cannabis-containing products as a food. The FDA defines food as "articles used for food or drink for man or other animals . . . and articles used for components of any such article." (See 21 U.S.C. § 321(f.) Clearly, the various baked goods and other cannabis-containing food products for sale in states where cannabis has been legalized fall under this definition. The benefit of this approach is that food products do not require manufacturers to follow the lengthy and expensive FDA drug approval process before marketing the product to consumers. Instead, foods have a separate federal regulatory scheme focused on disclosure to the consumer, as opposed to pre-market safety and efficacy testing. However, treating cannabis-containing edibles as food presents unique issues.

In states like Illinois that allow only medicinal cannabis use, the laws require the product to be labeled with the disclaimer, "not a food." But labeling an edible cannabis product as "not a food" to avoid the FDA food-labeling requirements, current Good Manufacturing Practices (cGMPs) and other regulatory requirements is a difficult proposition. Furthermore, even in those states where recreational cannabis use is legal (use not specific to the treatment of a disease or used to alleviate a symptom), and cannabis-containing foods are marketed as food, cannabis is still an ingredient of those food products under FDA regulations. Under § 321(f), above, and § 321(s) (defining food additives), the use of cannabis as an ingredient in an edible cannabis-containing food product would render the food "adulterated" under 21 C.F.R. § 342. Adulterated food items are subject to FDA detention proceedings and other enforcement actions, even if all other FDA requirements are fulfilled.

Cannabis as a drug

As everyone in the medical cannabis industry knows, the federal government, under the oversight of the Drug Enforcement Agency (DEA) classifies cannabis as a Schedule I Drug. Schedule I drugs are those

- "drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Schedule I drugs are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence."

Thus, the DEA has determined that cannabis is a significantly harmful substance, with no recreational or medical uses. The DOJ has echoed support for this position. The FDA's support of this position can be inferred by its review and approval of two cannabinoid drugs recently taken through the drug approval process (Marinol and Cesamet).

The FDA, like the DEA and Department of Justice, treats cannabis and cannabis derivatives as drugs that must be approved by the FDA before being marketed to consumers. Recently, the FDA approved some preliminary trials in the use of cannabidiol, or the oils derived from cannabis, in treating childhood epilepsy. Furthermore, the FDA continues to view any claims that a cannabis-containing product treats a disease (or symptoms of a disease such as pain) as a drug claim, requiring the manufacturer to adhere to FDA drug regulatory requirements. This includes filing an Investigational New Drug application (IND), engaging in the clinical trial process and the subsequent filling of a New Drug application demonstrating the efficacy and safety of the new drug. The FDA has also taken recent enforcement actions that reiterate its dedication to applying the IND process to cannabis-containing products. In February 2015, the FDA sent warning letters to six organizations selling 18 different products claiming to contain cannabidiol, a cannabis derivative.

In states like Illinois, where only medical use has been legalized, the Illinois legislative scheme treats cannabis edibles as drugs or dietary supplements when compared to the federal definitions for the same. (See the Illinois state Compassionate Use of Medical Cannabis Pilot Program Act, 410 ILCS 130/20.) This is evidenced by a number of terms within the Illinois statute, including the requirement that edible product labels state that the product is "not a food." Treating edible products as drugs, as required by state laws, exposes the product to the FDA requirements even though none of the state laws account for such regulatory compliance.

Cannabis as a dietary supplement

The third alternative to market entry for cannabis containing products is as a dietary supplement. The marketing of dietary supplement products is limited to structure function claims or health claims and depending on which the manufacturer wishes to make, the product is subject to different market-entry requirements.

If the product claims to support particular bodily functions or body structures, extensive clinical trials are not necessary, however there must be reliable scientific data/studies to support such claims. If the product's claims are related to a disease, then clinical work may be necessary to support those disease claims. Nevertheless, dietary supplement products are not required to undergo the lengthy and expensive safety and efficacy testing of a new drug and are regulated through the Food Center at the FDA.

Dietary supplements have their own set of regulations resulting from the Dietary Supplement Health and Education Act of 1994 (DSHEA), which places the responsibility for safety testing squarely on the shoulders of those companies making the supplement. Although the manufacturer may have to submit a New Dietary Ingredient application to the FDA, this process is much faster and less expensive than the process for new drug approval. However, the twist to marketing a dietary supplement is that once the product has entered the market, advertising claims related to that product are then regulated by the Federal Trade Commission (FTC).

If a manufacturer of cannabis-containing products wishes to market its products as a dietary supplement, marketing and labeling (which include claims concerning the product) must be a focus point. Ultimately, however, dietary supplements are also subject to the misbranding statutes in § 502.

Which door to choose?

The best possible solution will often be dictated by the market that the manufacturer wishes to reach and the data currently within that manufacturer's reach. While no one choice will render the product legal under federal law, businesses selling cannabis containing products or cannabis derivatives can take steps to minimize their liability.

At Thompson Coburn, the Cannabis Practice Group is able to provide counsel on these issues to the cannabis industry. Our attorneys, with years of FDA, federal regulatory healthcare compliance, land use and licensing experience can address your individual issues and recommend a best course of action for your company and your products.

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