

Navigating the Web of CBD Regulations



How to Assist Clients

BY AMANDA MILGROM



This article outlines federal regulations governing CBD and how lawyers can assist clients in navigating this challenging and fast-changing landscape.

Products made with cannabidiol, commonly known as CBD, have become ubiquitous. CBD infiltrates society through the food and beverages on our shelves, the lotions and oils at our local drug stores, and the dog treats at pet stores. The CBD industry is projected to be worth up to \$20 billion by the year 2024.¹ Even the national drugstore chain CVS is selling CBD products in at least eight states.²

Many producers and sellers of hemp and CBD products are incorporating CBD into their existing products to make new products. They rely on their lawyers to help them navigate a complex, and seemingly contradictory, collection of laws and regulations. It is thus critical for lawyers to be involved in every stage of the marketing process.

This article takes an in-depth look at federal CBD regulations. It covers how companies should advertise hemp-derived CBD products and what they should include, or not include, on their product labels. Although this article is limited to federal regulations and labeling standards, these federal standards do not necessarily preempt state law, so applicable state laws may still apply.³

Federal Oversight of CBD

Federal regulation of CBD presents a complicated legal analysis. Four independent federal entities have direct oversight of CBD: the U.S. Congress, the U.S. Drug Enforcement Administration (DEA), the U.S. Food and Drug Administration (FDA), and the Federal Trade Commission (FTC). Each has its own applicable laws and rules, and its own interpretation of the legal authority.

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For example, Congress removed industrial hemp and industrial hemp derivatives from the list of Schedule 1 drugs in 2018. Schedule 1 drugs are defined as drugs with no currently accepted medical use and a high potential for abuse.⁴ This means that producing and selling industrial hemp and its derivatives (including CBD) are now legal under federal law. In addition, Congress has deprived the DEA of funds to prohibit the transport, processing, sale, or use of industrial hemp grown in accordance with federal law. This takes the teeth out of DEA’s efforts against CBD. The DEA, however, still considers CBD to be a Schedule 1 drug under the Controlled Substances Act and enforces its use as illegal.

Meanwhile, the FDA also regulates cannabis-related products, including CBD. The FDA has declared that adding CBD to food products and selling CBD as a dietary supplement violates FDA regulations. Therefore, the sale of CBD is currently not permitted across state lines.

Accordingly, the legal landscape is currently a confusing maze of rules and regulations; whether the sale of hemp-derived CBD is lawful depends on the federal entity involved in the transaction. Because the FDA considers the sale of CBD in food or its advertisement as a dietary supplement to be illegal, and the DEA

views CBD as a Schedule 1 drug, it is impossible to completely avoid the legal risks of selling CBD in interstate commerce. Yet while various interpretations of the law are technically at odds with one another, a company wishing to sell CBD products within a state should be able to avoid most thorny compliance issues by following the recommendations below.

Congress Enacts Legislation

Last year, Congress passed the Agricultural Improvement Act of 2018 (the 2018 Farm Bill), which replaced the Agricultural Improvement Act of 2014. The 2018 Farm Bill was the first piece of federal legislation to legalize hemp.⁵ It established a new category of cannabis classified as “hemp”—defined as cannabis and cannabis derivatives with extremely low (no more than 0.3% on a dry weight basis) concentrations of delta-9-tetrahydrocannabinol (THC).⁶ Previous legislation on the subject, the 1937 Marihuana Tax Act and the 1970 Controlled Substances Act, failed to distinguish between cannabis and hemp plants. As a result, before the 2018 Farm Bill, hemp was banned and classified as a Schedule 1 drug alongside cannabis.

The 2018 Farm Bill also amended the Controlled Substances Act by declassifying hemp as a Schedule 1 drug, but this did not legalize CBD generally. CBD remains a Schedule 1 drug under federal law subject to a narrow exception: if hemp is produced by a licensed grower in a manner consistent with the 2018 Farm Bill and associated state and federal regulations, it is legal for production and sale.⁷ All other CBD products remain Schedule 1 substances under federal law and are thus illegal. Clients must ensure their producers are in compliance with the 2018 Farm Bill, because if they aren't, the client is illegally selling a Schedule 1 drug.

In addition, Congress passed the Omnibus Appropriations Bill, which prevents the DEA from using any funds

to prohibit the transportation, processing, sale, or use of industrial hemp, or seeds of such plant, that is grown or cultivated in accordance with subsection section 7606 of the Agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated.⁸

This provision greatly curtails DEA's ability to prosecute any legal producers or sellers of hemp-derived CBD.

The DEA's Perspective

Despite Congress's decision to legalize hemp, the DEA continues to place significant obstacles in the path of hemp cultivation, production, and sales. In 2016, it promulgated a rule stating

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that “marihuana extract” (which includes hemp extract) containing one or more cannabinoids is illegal, even if the extract does not contain THC.⁹

In 2018, following the passage of the 2018 Farm Bill, the DEA reinforced that CBD remains a Schedule 1 drug.¹⁰ Essentially, this means that all CBD—including CBD derived from hemp—remains banned by the DEA as a substance “with no currently accepted medical use and a high potential for abuse.”¹¹

The FDA's Restrictions

At the same time that Congress passed the 2018 Farm Bill, it explicitly preserved the FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the federal Food, Drug, and Cosmetic Act (the Act) and section 351 of the Public Health Act.¹² In response, the FDA quickly issued a statement explaining that although hemp is no longer an illegal substance under federal law, the FDA will continue to regulate cannabis and hemp products while it conducts research on the health benefits or potential dangers of CBD.¹³

Therefore, per the FDA's regulations, cannabis products marketed with a claim of therapeutic benefit and CBD-infused food or beverages, regardless of whether the CBD is hemp-derived, must be FDA approved before they can be sold. Practically speaking, this means that the FDA has prohibited the introduction of CBD-infused food and drinks and CBD dietary or nutritional supplements into interstate commerce. However, the FDA has not strictly enforced these rules, as evidenced by the plethora of CBD products being sold across state lines, even on mainstream marketplaces like Amazon.¹⁴ Instead, the FDA has been sending warning letters to CBD companies it contends are making egregious health claims about CBD, such as claims that CBD can treat or cure cancer or hair loss. And notwithstanding its regulatory restrictions on CBD products, the FDA has approved a specific use of CBD.

In June 2018 the FDA approved a CBD prescription drug product, Epidiolex, to treat rare, severe forms of epilepsy.¹⁵ It is the first, and to date only, FDA-approved CBD product. Because CBD is the active ingredient in Epidiolex, the FDA has stated that CBD cannot be added to food or marketed as a drug without going through the FDA's established drug approval processes.¹⁶ While its approval of Epidiolex briefly caused the market to believe that the FDA would approve all CBD products, the FDA quickly quashed that understanding and reinforced its non-approval of CBD infused food, drinks, and dietary supplements.

But CBD producers and sellers yet have options. The FDA has succumbed to intense pressure from CBD producers and sellers and

is working diligently to determine the final legal status of CBD. It held a public hearing on May 31, 2019 for stakeholders to share their experiences and challenges with products containing cannabis and CBD, including information related to product safety, as well as to solicit input relevant to the agency's regulatory strategy related to existing products.¹⁷ As part of that hearing, the FDA opened a docket for public comments.¹⁸ The FDA is specifically investigating CBD's effects on the body, such as liver toxicity; the effects of cumulative exposure to CBD across a broad range of products; the effects of CBD on special populations; and the safety of CBD for animals.¹⁹ In addition, the FDA is forming a high-level internal agency working group to explore potential pathways for the lawful marketing of dietary supplements and conventional foods containing CBD.

Concerns with CBD Sales

In the context of CBD sales, the FDA is primarily concerned with sellers making unproven claims about using CBD to treat serious or life-threatening diseases, particularly claims inducing patients to forgo effective, available therapies and opt instead for a product with no proven value that may cause serious harm.

The FDA's enforcement priorities are illustrated in its recent 2019 warning letters to at least five CBD companies in response to unsubstantiated claims relating to over a dozen products. The claims span multiple webpages, online stores, and social media websites. According to the FDA, these companies made "unfounded, egregious claims" about their products' ability to limit, treat, or cure cancer, neurodegenerative conditions, autoimmune diseases, opioid use disorder, and other serious disorders, without

sufficient evidence and without required FDA approval.

Specifically, on March 28, the FDA issued warning letters to Nutra Pure LLC, of Vancouver, Washington, for illegally selling CBD products online with unsubstantiated health benefits in violation of the Act;²⁰ PotNetworkHoldings, Inc., of Fort Lauderdale, Florida, for taking orders for various CBD food products and advertising them as a drug;²¹ and Advanced Spine and Pain, LLC, of Mount Laurel, New Jersey, for selling CBD products online, advertising their unsubstantiated health benefits in violation of the Act, and advertising them as drugs.²² On July 22, the FDA issued a warning letter to Curaleaf Inc. of Wakefield, Massachusetts for illegally selling unapproved products containing CBD online with unsubstantiated health benefits claims on its website (the Curaleaf warning



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RECOMMENDATIONS FOR COMPANIES SELLING CBD PRODUCTS

To avoid attracting the attention of the FDA and FTC, CBD companies should:

- Replace “CBD” or “CBD Infused” with “Hemp Infused” or “Hemp Extract” on product packaging and the company’s advertising materials and website.
- Avoid discussing specific health benefits of CBD. Instead, use generic words addressed to common symptoms that the majority of the population experiences, such as “known for supporting the mind and body,” “helps maintain good health,” and “helps with calm, sleep, and recovery.”
- Remove all references to the product being a “food supplement,” “dietary supplement,” or “nutritional supplement” from all advertising and packaging; these terms are red flags for the FDA.

letter).²³ The FDA informed Curaleaf that its advertisements for its “CBD Lotion,” “CBD Pain-Relief Patch,” “CBD Tincture,” and “CBD Disposable Vape Pen” are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Act.²⁴ The FDA also found that Curaleaf intended to market its CBD in violation of the Act. And on October 10, 2019, the FDA issued a warning letter to Rooted Apothecary, LLC of Naples, Florida for selling unapproved and misbranded drugs in the form of CBD oil, lotions, and capsules.²⁵

These letters, along with the statement by prior FDA Commissioner Scott Gottlieb, M.D., demonstrate that the FDA will be identifying and pursuing companies that target vulnerable populations and claim their CBD products prevent, diagnose, treat, or cure serious diseases, such as cancer, Alzheimer’s disease, psychiatric disorders, and diabetes.²⁶

CBD Cannot be Advertised as a Drug

Prescription and non-prescription drugs must generally receive premarket approval through the FDA’s lengthy new drug application process, or conform to a “monograph” for a particular drug category as established by FDA’s over-the-counter (OTC) drug review.²⁷ The FDA considers a product to be a “drug” when its marketing and advertising suggests that it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or because it is intended to affect the structure or function of the

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body.²⁸ CBD was not an ingredient considered under the OTC drug review, and an unapproved new drug cannot be distributed or sold in interstate commerce. Thus, any advertising that discusses the potential health benefits of CBD creates a substantial risk that the FDA will classify the product as a drug.

The FDA has considered the following statements targeting both specific diseases and more general health conditions as unlawful marketing of CBD as a drug:

- “Natural cannabinoids, such as CBD (cannabidiol), have been shown in research to have therapeutic possibilities in helping diabetes.”²⁹
- “And there have been scores of research studies into CBD’s effects on a myriad of conditions from epilepsy to Alzheimer’s, autism, PTSD, and much more.”³⁰
- “[E]vidence that the therapeutic efficacy of CBD in the treatment of anxiety-related disorders was pronounced, particularly in the areas of conditioned fear responses, stress, generalized anxiety disorder, social phobia, panic disorder, PTSD, and OCD.”³¹
- “CBD is a very broad treatment options that targets multiple symptoms and ranges present with depression.” [sic]³²

To comply with the Act, CBD sellers must avoid making these types of statements.

CBD Cannot be Advertised as a Dietary Supplement

Based on available evidence, the FDA has concluded that CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the Act.³³ This exclusion applies to substances such as CBD that are an active ingredient in a drug that has been approved under section 505 of the Act or substances authorized by the FDA to be investigated as a new drug for which substantial clinical investigations have been instituted and made public. Notwithstanding a substance’s exclusion from the dietary supplement definition under section 201(ff)(3)(B) of the Act, the FDA has discretion to issue a regulation finding that such substance would be lawful under the Act. To date, no such regulation has been issued for CBD.³⁴

The FDA's recent warning letters indicate the following types of statements are evidence that a seller intended to market a CBD product as a dietary supplement:

- The directions for use begin with the phrase “[a]s a hemp supplement . . .”³⁵
- The product is labeled with the phrase “nutritional supplement.”³⁶

CBD Cannot be Advertised as Food

The FDA prohibits the sale of any food to which CBD has been added. The FDA has determined that CBD is not “food,” because CBD is the active ingredient in the approved drug product Epidiolex, and the FDA prohibits the introduction of food into interstate commerce to which an FDA-approved drug has been added. In addition, the existence of substantial clinical investigations regarding CBD has been made public. “Based on available evidence, FDA has concluded that section 301(ll) prohibits the introduction into interstate commerce of any food to which CBD has been added.”³⁷

Because the FDA prohibits the sale of food infused with CBD, sellers should replace “CBD-infused” with “Hemp Infused” or “Hemp Extract” on their product labels and websites.

Consequences of Violating FDA Requirements

A client who may be in breach of FDA requirements will likely face an FDA warning letter informing it of the violation and instructing it to fix the problem within a certain timeframe. This may entail actions ranging from product repackaging to the recall of unsold product. The FDA follows up to ensure that a company's corrections are adequate.

The FDA has other enforcement tools at its disposal. For example, it can

- force a company to recall both sold and unsold packages of a noncompliant product;
- seize an FDA-regulated product because it is adulterated and/or misbranded within the meaning of the Act; and
- recommend, in appropriate cases, criminal prosecution. Criminal sentences can include fines ranging from \$100,000 (for misdemeanors that did not result in

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death) to \$500,000 (for misdemeanors resulting in death and felonies), and up to one year in jail.³⁸

Although the FDA has these various enforcement tools at its disposal, it is unlikely to employ them generally against CBD sellers because it has not done so in the past, and it has recently begun discussions on whether to legalize the sale of CBD in food or as a dietary supplement. But the FDA remains focused on enforcing its laws against companies making egregious statements about CBD's health benefits. And its warning letters to such companies may carry consequences more severe than simply removing unlawful language from websites and packaging materials. For example, after it issued the Curaleaf warning letter, Curaleaf's shares fell more than 7%, and other cannabis stocks fell as well.³⁹ In addition, CVS plans to remove Curaleaf's products from its shelves following the FDA's warning.⁴⁰

FTC Regulation of CBD Products

The FTC also plays a role in regulating CBD as the federal agency in charge of regulating



advertising and marketing. Under the FTC Act, 15 USC §§ 41 et seq., it is unlawful to advertise a product as preventing, treating, or curing human disease unless the seller possesses competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies substantiating that the claims are true at the time they are made.⁴¹ A seller who makes or exaggerates such claims through a website or other means without rigorous scientific evidence to substantiate the claims may face legal action for an injunction or an administrative cease and desist order. An order also may require that the seller pay back money to consumers.⁴²

FTC Action against CBD Sellers

Thus far in 2019, the FTC’s enforcement actions against CBD sellers have been limited to joining in FDA warning letters to four companies

marketing products containing CBD to treat and cure a variety of serious diseases and conditions,⁴³ and sending its own warning letters to additional companies that sell oils, tinctures, capsules, and creams containing CBD, which are advertised as curing or treating serious diseases and health conditions.⁴⁴ According to the letters, the FTC believes that the advertised products may violate the FTC Act by making false or unsubstantiated health claims.⁴⁵

Although the FTC has not yet taken an aggressive position against CBD products, it remains important for clients to comply with FTC requirements. For example, statements and representations that may be found misleading, deceptive, without substantiation, and/or fraudulent are specific areas of FTC concern.⁴⁶ The FTC’s recent warning letters also indicate that federal agencies generally are paying more attention to the CBD industry.

Conclusion

CBD regulations are complicated, but many companies are nevertheless jumping headfirst into the CBD market with no real understanding of the web of laws governing the marketplace. Lawyers can play a critical role in helping these companies understand and successfully navigate the risks of the CBD market. **CL**



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29. PotNetworks Holdings Warning Letter, *supra* note 21.

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