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1. *CBD Regulatory Landscape and Enforcement Risks*
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# *CBD Regulatory Landscape and Enforcement Risks*


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This practice note provides an overview of the federal and state agencies regulating hemp and cannabidiol (***CBD***) products, as well as an overview of current federal and state regulations and requirements for the marketing and sale of ***CBD*** products.

This practice note covers the following:

- *Federal Legalization of Industrial Hemp and **CBD***
- *USDA Oversight*
- *FDA Oversight*
- *FTC Oversight*
- *State Regulation of Hemp and **CBD***
- *Class Action Lawsuits*
- *Navigating the Patchwork of State and Federal Regulations*

For more information about cannabis products, see *Cannabis Resource Kit*.

This practice note does not discuss marijuana regulation. For information on state regulation of marijuana, see *Medical and Recreational Marijuana State Law Survey*.

## Federal Legalization of Industrial Hemp and *CBD*

Prior to 2018, industrial hemp and industrial hemp-derived compounds, such as ***CBD***, were considered “marihuana” under federal law. Until that time, marihuana compounds were identified as Schedule 1 substances under the Controlled Substances Act of 1970, *21 U.S.C. §§ 801–971* (Ch. 13 Drug Abuse Prevention and Control) (CSA).

The Agricultural Improvement Act of 2018 (2018 Farm Bill), which became U.S. law in December 2018, expressly removed “hemp” from the definition of “marihuana” under the CSA, thereby legalizing industrial hemp and industrial hemp-derived compounds. Under the 2018 Farm Bill, hemp was defined as “the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis.”

Along with legalizing industrial hemp, the 2018 Farm Bill also assigned to the U.S. Department of Agriculture (USDA) federal regulatory authority for production of industrial hemp. Importantly, however, the 2018 Farm Bill also included a carve-out provision under which the U.S. Food and Drug Administration (FDA) retained its ability to regulate products subject to the federal Food, Drug and Cosmetic Act (FDCA).

**USDA Oversight**

The 2018 Farm Bill tasked the USDA with promulgating regulations and guidelines to establish and administer a program to encourage production of hemp in the United States. The USDA issued its interim final rule for hemp production in October 2019. The USDA interim rule is effective from October 31, 2019 through November 1, 2021, at which point it will be replaced by a final rule. The interim rule, which regulates the growth and production of hemp (but not ***CBD*** products), allows states and Indian tribes the option of either submitting to the USDA for approval of a proposed hemp regulation plan or agreeing to submit to the USDA's general requirements. According to the USDA proposed regulations, all state and tribe plans submitted to the USDA must include the following:

- A description of the land used for hemp production
- Sampling and testing procedures for the delta-9 tetrahydrocannabinol (THC) in the hemp crop
- A plan for the disposal of hemp containing more than the allowable 0.3% THC
- Procedures for the inspection of hemp producers and their hemp crop –and–
- Maintenance of a database including information on state hemp production, land use, and producer information

The USDA rule also notably prohibits states from interfering with the interstate transportation of industrial hemp grown pursuant to a USDA-approved state-hemp production plan. However, as mentioned, the USDA rule does not govern the marketing, sale, and production of ***CBD*** products. Oversight of the marketing, sale, and production of ***CBD*** products remains with the FDA.

**FDA Oversight**

While the 2018 Farm Bill provided the USDA with oversight of hemp production, it also left intact the FDA's authority over certain hemp and hemp-derived products (cosmetics, dietary supplements, food, and drugs). The 2018 Farm Bill explicitly did not amend the FDCA, meaning that hemp and hemp products must be compliant with the FDCA and its related regulations.

The FDA's regulation of ***CBD*** products varies depending on whether the product is a cosmetic, a drug, or a food or dietary supplement.

***CBD* Cosmetics**

Section 201(i) of the FDCA, 21 C.F.R. § 321(i), defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on or introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance." Although certain ingredients are prohibited from inclusion in cosmetics under the FDCA, that is not the case for hemp or hemp-derived ingredients, including ***CBD***. However, even though cosmetics may contain hemp or hemp-derived compounds, under FDA authority, these products must still comply with FDCA requirements—namely, products may not be "adulterated" or "misbranded."

Under Section 601 of the FDCA, *21 U.S.C. § 361*, a cosmetic product is adulterated under the FDCA, if, among other reasons, "it contains any poisonous or deleterious substance which may render it injurious to users." A cosmetic product is misbranded under Section 602 of the FDCA, *21 U.S.C. § 362*, "if its labeling is false or misleading" or if it fails to comply with other regulatory requirements for labeling.

As discussed later in this practice note, the FDA has focused its enforcement efforts in the ***CBD*** space on products that bear claims that render the products misbranded or unapproved new drugs under the FDCA. That said, pursuant to the FDCA, hemp and hemp-derived compounds, such as ***CBD***, may be legally marketed and sold as cosmetics under federal law if they comply with FDA regulations.

***Food and Dietary Supplements***

Unlike cosmetics, the FDA has repeatedly and explicitly stated that ***CBD*** may not be added to food and dietary supplements because under the FDCA, a food or dietary supplement may not contain ingredients that are also active ingredients in an FDA-approved drug product.

In 2018, the FDA approved ***CBD*** as the active pharmaceutical ingredient in Epidiolex, a seizure medication for children. This meant that under the FDCA, ***CBD*** could no longer be added to food or dietary supplements, absent additional guidance from the FDA. In fact, in a series of responses to *frequently asked questions* about ***CBD*** regulation, the FDA made its position even clearer that dietary supplements cannot lawfully contain ***CBD*** and that such products are regarded as unapproved new drugs.

However, in December 2018, the FDA determined that certain parts of the hemp plant (hulled hemp seed, hemp seed protein powder, and hemp seed oil) are Generally Recognized as Safe (GRAS) for human consumption and, thus, may be lawfully marketed in food products, so long as very specific criteria set forth in the GRAS Notification Letters are met. This criterion includes, but is not limited to, the specific types of food products to which the GRAS substances may be added as well as the technical requirements for processing the GRAS substances.

***FDA Enforcement Actions***

The FDA has issued several warning letters to companies manufacturing ***CBD*** products that the FDA deems misbranded or adulterated in violation of the FDCA. Typically, the FDA has sent these letters to companies selling products that the FDA considers misbranded based on the inclusion of unlawful health claims in marketing materials. For example, the FDA has questioned the following health claims:

- "***CBD*** has been demonstrated to have properties that counteract the growth of [and/or] spread of cancer." July 22, 2019 Warning Letter to Curaleaf, Inc.
- "[P]ossible uses for ***CBD*** include helping with skin problems such as acne, autism, ADHD, and even cancer. It's often used in conjunction with traditional treatments to provide extra help. Children can use high amounts of ***CBD*** safely and without any risk." October 10, 2019 Warning Letter to Rooted Apothecary LLC.
- "***CBD*** was administered after onset of clinical symptoms, and in both models of arthritis the treatment effectively blocked progression of arthritis." March 28, 2019 Warning Letter to PotNework Holdings, Inc.

Companies receiving warning letters from the FDA have 15 days from receipt to respond with evidence of how they will correct the violations. Failure to respond or correct the violations may result in further legal actions including product seizure and injunction of sales.

For more information about FDA warning letters addressing ***CBD*** and other FDA-regulated products, see *FDA Warning Letters Tracker*.

**FTC Oversight**

Although the 2018 Farm Bill did not explicitly provide the Federal Trade Commission (FTC) with oversight of hemp and hemp-derived products, the FTC has remained active in monitoring and attempting to regulate the market because of its authority over advertisements. Under the FTC Act, 5 U.S.C. §§ 41–58, it is unlawful to advertise that a product can prevent, treat, or cure human disease unless the claims are substantiated (at the time they are made) by reliable and competent scientific evidence. Therefore, pursuant to the FTC Act, the FTC has issued numerous warning letters (often jointly with the FDA) to ***CBD*** companies making various health claims without scientific evidence and clinical studies to support the claims.

For more information on the FTC Act and regulation of advertising by the FTC, see *FTC Enforcement of Consumer Protection Laws* and *FTC Enforcement of Advertising Claims*.

**State Regulation of Hemp and *CBD***

Although the USDA has provided guidance on hemp production and the FDA has provided some guidance on the use of ***CBD*** in FDA-regulated products, a comprehensive and uniform regulatory scheme for hemp products does not exist at the federal level.

In the absence of federal guidance, some states have developed their own requirements for the sale and marketing of ***CBD*** products, including rules for testing and labeling ***CBD*** products. However, only a handful of states have developed such rules, while other states are either working to develop rules or have merely accepted the realities of an unregulated ***CBD*** market while awaiting further FDA guidance.

***CBD*** companies doing business in a state—including selling or marketing ***CBD*** products—are subject to the requirements of that state. In most states, ***CBD*** product regulation is handled by the state's Department of Agriculture or Department of Health.

***CBD Product Labeling / Testing Requirements***

In states where comprehensive regulatory schemes have been adopted (e.g., Utah, Florida, and Colorado), certain core requirements for ***CBD*** product labeling and testing requirements have been consistently included in the state regulatory schemes. State requirements typically include:

- A requirement that all ***CBD*** products be registered with the state (this responsibility typically falls on the manufacturer, and not the retailer, of the ***CBD*** product)
- A requirement that a Certificate of Analysis for the product's source of hemp be available and include:
    - The ***CBD*** and THC levels of the tested hemp plant by dry weight
    - Test results indicating the presence of any solvents, pesticides, microbials, and heavy metals
    - The hemp batch ID number
    - The date the COA was issued –and–
    - The testing laboratory's method of analysis
- A requirement that product labels conform with FDA regulations (e.g., no unsupported health claims) –and–
- A requirement that product labels contain a scannable bar code, QR code, or website containing a link to the Certificate of Analysis

Despite the lack of uniform testing and labeling requirements across the states, a company can generally lessen its risk of both state and federal enforcement actions by ensuring that ***CBD*** products are labeled and tested in compliance with the above requirements.

Companies should also ensure that there are no further state requirements, in addition to the above. As discussed below, state regulations are constantly shifting and, to mitigate risk and ensure compliance, companies should actively monitor and comply with state regulatory developments.

***State Regulation of CBD in Food***

Although the FDA has explicitly held that ***CBD*** may not be added to food products in interstate commerce, some states (e.g., Utah, Maine, and Colorado) have, in direct contravention of FDA guidance, explicitly legalized the sale and marketing of ***CBD*** food products. Other states (e.g., California, Washington, and New York) have also explicitly stated that ***CBD*** food products are illegal until the FDA issues further guidance on the matter.

Despite the FDA's stance on ***CBD*** food products, it is possible that FDA will defer to state regulations as it continues to develop a comprehensive regulatory scheme. However, the interstate transportation of ***CBD*** food products implicates federal law and thus, to avoid the risk of federal enforcement actions, ***CBD*** food products should be manufactured, produced, and sold only within the boundaries of the state where legal. Even then, the federal government is likely to find an interstate commerce hook based upon use of the internet, federal mail service, or components of the product. For example, if the paper used in the labeling of a product was made out of

state or with ink from out of state, that is likely to be enough of a hook to constitute interstate commerce and subject a company to federal oversight and enforcement efforts.

**Class Action Lawsuits**

Companies must accurately market the amount of ***CBD*** in their products. Plaintiffs across the country have filed a spate of federal class actions claiming that companies are misrepresenting, and thus falsely advertising, the actual amount of ***CBD*** in their products. In most of these actions, plaintiffs claimed that companies have overstated the actual amount of ***CBD*** in their products. In one case, the plaintiff alleged that a company falsely claimed its products to be THC free. Darrow v. Just Brands USA, Inc. et al, No. 1:19CV07079 (N.D. Ill. Oct. 28, 2019); Ahumada v. Global Widget LLC No. 1:19-cv-12005-ADB (Mass. Sept 24, 2019).

In addition, companies must take care to monitor where they are selling their products and whether the products are legal in those jurisdictions. Several lawsuits filed in federal court in California by consumer-plaintiffs have stated that the plaintiffs would not have purchased the products if they understood them to be illegal in California at the time of purchase. McCarthy v. Charlotte's Web Holdings, Inc., No. 5:19-cv-07836 (N.D. Cal. Nov. 30, 2019); Dasila v. Infinite Product Co., No 2:19-cv-10148 (C.D. Cal. Nov. 27, 2019).

**Navigating the Patchwork of State and Federal Regulations**

***CBD*** regulations on both the state and federal levels are constantly evolving. It can therefore be incredibly difficult to properly assess and ensure that hemp and hemp-derived products are complying with all applicable regulatory requirements.

However, companies in this industry can substantially lower the risk of state and federal enforcement actions against them by taking the following steps:

- Ensure that products comply with all applicable FDA regulations, including, but not limited to, refraining from making unlawful health claims about products containing ***CBD***.
- Avoid adding ***CBD*** products to food or dietary supplements. If companies choose to do so, they should ensure that production and sales are confined solely to a state in which such products are legal and, even then, should understand that there is still federal legal risk associated with such actions.
- Review and follow all applicable state regulations concerning ***CBD*** products, including, but not limited to, complying with all labeling and testing requirements.
- Ensure that all ***CBD*** products, and the hemp crop from which the ***CBD*** was derived, was tested by a reputable, independent laboratory. Additionally, maintain all certificates of analysis and documentation regarding the testing processes.
- Ensure that claims set forth in all labeling, packaging, marketing, and advertising of ***CBD*** accurately reflect any test results and are otherwise fully substantiated before the claims are made.

Unless and until the FDA issues comprehensive regulations for the testing, labeling, and marketing of ***CBD*** products, companies producing, selling, and marketing ***CBD*** products will have to grapple with the patchwork of conflicting state and federal regulations and the risk of class action litigation. However, ***CBD*** companies can avoid the pitfalls of these regulations and potential regulatory enforcement by reviewing and staying abreast of new developments in the ever-changing legal landscape.

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