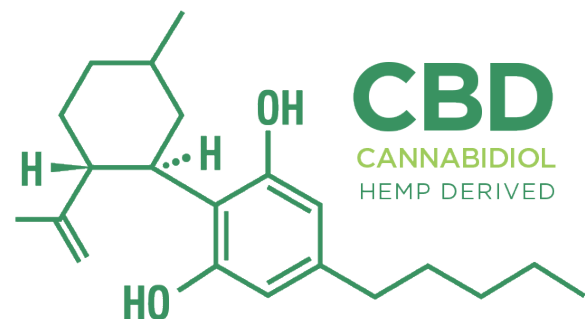


# What Do You Need to Know For an FDA-Compliant CBD Product Label?

## Introduction

For those offering a CBD-based product or thinking about joining this fast-growing industry, the conflicting array of regulations can be daunting. Since the rapidly evolving Federal laws governing how to produce, market, and sell these goods significantly impact how to label CBD products, this white paper is intended to provide a better understanding of how to comply with the current regulations. The topics covered include the impact of the 2018 Farm Bill on the Federal legalization of hemp and CBD; a look at the growth of the CBD market; changing FDA guidelines for what is legal to sell; and how to comply with labeling requirements. *Please note: SixB Labels Corporation provides this quick reference to our clients and is not responsible for any errors. Please direct all questions to [www.FDA.gov](http://www.FDA.gov).*

## What is CBD?



CBD is an abbreviation of cannabidiol, a naturally occurring compound, one of a number extracted from the cannabis plant. Tetrahydrocannabinol – abbreviated to THC – is the psychotropic compound in marijuana that can alter a user's perceptions of reality or cause euphoria. THC is taken from the resinous flowering bud tops and leaves of the plant, while the stalks and sterilized seeds are normally the source for CBD. However, producers can also obtain CBD from the THC portions, which might yield a mixture of the two compounds. According to online business and lifestyle magazine Quartz, although CBD is not psychotropic, some maintain that it offers therapeutic benefits, leading products containing CBD to be marketed with a number of health claims.<sup>1</sup>

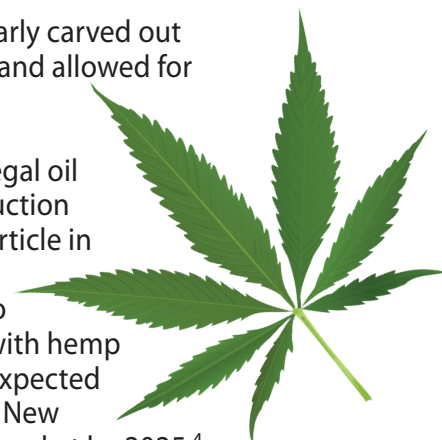
## Why is the CBD Market Booming?

The most recent market boom was sparked by the passage of the 2018 Farm Bill, an \$867 billion agricultural funding bill which included a provision to federally legalize the growing and processing of industrial hemp and its derivative, CBD. This piece of legislation eliminated industrial hemp's former status as a "Schedule I" drug under the Controlled Substances Act. The result was to take the production of industrial hemp and the manufacture of CBD out of the control of the Drug Enforcement Agency (DEA) and put it under the Food and Drug Administration (FDA).

As far back as 2015 and before, hemp-derived CBD was being sold even while its legal status in the United States was uncertain, despite the fact that the 2015 Farm Act permitted hemp cultivation, regulated by the Department of Agriculture, in individual states. It allowed licensed farmers to grow hemp in states that adopted the pertinent Federal guidelines, and they eventually were cultivating thousands of acres of Federally legal hemp throughout the U.S. Read more at the National Hemp Association website.<sup>2</sup>

As a result, there has existed for years a patchwork of statutory and case law that clearly carved out exceptions to the illegality of cannabis. These exceptions, though narrow, were real, and allowed for CBD to be produced and sold under certain circumstances.

Extraction from hemp with generally 0.3% or less of TCH by dry weight produces a legal oil product, rich in CBD and low in THC. Formerly harvested for food, beverages, construction materials and beauty products, hemp is now being grown primarily for CBD oil. An article in the online business magazine The Hustle states that the planting of industrial hemp increased 368% from 2018 to 2019, outpacing all other crops.<sup>3</sup> The article goes on to state that, per the U.S. Department of Agriculture, the amount of farmland planted with hemp quadrupled in the past year. For more context, consider that an acre of soybeans is expected to make a farmer \$500, while an acre of hemp could be worth \$30,000. According to New Frontier Data, this rapidly expanding industry is expected to grow into a \$30 billion market by 2025.<sup>4</sup>



# What Do You Need to Know For an FDA-Compliant CBD Product Label?

## How is the Law Treating the Marketing of CBD Products?

With the passage of the above-mentioned 2018 Farm Bill, in states with legalized medical and/or recreational marijuana, CBD is normally legal to buy and sell. However, state and local laws appear slow in catching up to Federal legalization. As a result, despite all the online mail-order sites stating that CBD and its derived products are legal in all 50 states, the details on the ground are more complicated.

Legal interpretations and enforcement actions still vary, both from state to state, and depending on whether the CBD in question is extracted from marijuana or hemp. For example: Kentucky and Oregon farmers trucking industrial hemp through Oklahoma and Idaho might face arrest and prosecution by state or local police for “drug trafficking”; or shop owners in Texas, Ohio or Nebraska might have their hemp plants or CBD products confiscated by local police. This happens when certain states hold that industrial hemp or CBD that contains any amount of THC is just as illegal as marijuana.

Even municipalities make their own local laws. Austin, Texas permits stores to sell CBD products while Duncanville, Texas – per the NY Times – only recently dropped an enforcement action against a shop owner for selling and possessing hemp and CBD products.<sup>5</sup> All this has resulted in an overwhelming patchwork of contradictory regulations for producers and consumers, especially because some of the more liberal CBD laws appear to clash with Federal rules. A recent Colorado law states that all parts of the hemp plant are legal to add to food for sale. And Missouri, which approved the sale of medical marijuana before this white paper was published, now allows CBD to be added to alcohol.

Since 2018, shops and restaurants have been selling CBD as an additive in food, tea, soda, beer, honey and dog treats. Salons have offered CBD-infused topical products, such as lotions and creams. And product labels, websites and social marketing platforms have touted CBD as a treatment for everything from joint pain, depression, and insomnia to cancer, epilepsy, and Alzheimers. Products with health claims have been marketed and sold as tinctures, oils, gummy candies, lollipops and more. But much of this will have to change, at least in the near future.

As state laws continue to evolve, it is vital to stay abreast of the regulations. No one wants to become subject to enforcement actions by the FDA. It is legal to sell CBD products online in all 50 states of the US as long as the oil is sourced from industrial hemp and the THC content is at or below 0.3%. Sellers must also comply with any additional regulations that are specific to their area. In addition, marketing and selling CBD made from legal, industrial hemp, in a state with a state-run CBD agricultural program, is legal. Selling it across state lines, though, means that manufacturers and distributors may be confronted with a variety of legal constraints.




## Is Curaleaf's Warning The Writing On The Wall?

Out of a concern for public health and safety in an unregulated CBD market, the FDA recently sent a warning letter to Curaleaf, a publicly traded CBD company, for allegedly misbranding their products and making “unsubstantiated health claims” in their marketing. Most of the claims with which the FDA took exception were from articles or blog posts on Curaleaf’s website, as well as from their Twitter and Facebook accounts. The claims were for products such as a vape pen, to be used for chronic pain, or a “soothing tincture for chronic pain.”

The FDA has sent this sort of warning letter to a number of companies in order to make it clear that no drug claims are allowed for CBD products. Curaleaf has since removed the statements in question from their marketing materials and social media accounts.

For more information, read the article in Cannabis Industry Journal.<sup>6</sup>

<p>Base Ingredients: Alcohol, Purified Water, Carboxymethyl Cellulose, Organic Ilex, Phenoxethanol, Methylparaben, Butylparaben, Ethylparaben, Propylparaben, Isobutylparaben, Tocopheryl Acetate (Vitamin E), Triethanolamine, Hemp Extract Oil</p> <p>CBD Soothing ICE is a mentholated gel product that is cooling to the applied area. It provides immediate relief that is long lasting. It absorbs quickly and leaves no greasy residue.</p> <p>0.0% THC</p>	 <p><b>READY AND WELL</b></p> <p><b>SOOTHING ICE</b></p> <p>COOLING RELIEF DEEP AND LONG LASTING PENETRATION</p> <p><b>2 OUNCE</b></p>	<p>Great anti-inflammatory properties. Feels great on warm and worn muscles and joints. Positive impact on minor aches, pains, bruising, muscle strains and more. Do not apply more than 4 times daily.</p> <p>Essential Oils: Camphor - for pain, itching, fungal infections Tea Tree - dry skin, eczema, oily skin, itchy skin, inflammation, infections, cuts, wounds, acne</p> <p><b>300 MG TOTAL CBD</b></p>
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# What Do You Need to Know For an FDA-Compliant CBD Product Label?

## What Is The Nationwide Legality, For Sale Or Purchase, Of CBD?

### CBD Illegal by State Law, Despite the 2018 Farm Bill:

Idaho, Nebraska, South Dakota

### CBD-Unfriendly/Hostile Environment, Due to Enforcement:

Alabama, Georgia, Iowa, Louisiana, Mississippi, North Dakota, Ohio, South Carolina, Texas, Wyoming

### CBD Legal With Restrictions:

Arizona

Arkansas

Delaware (only hemp derived)

Florida

Kansas (but only with 0% THC content)

Illinois (enforcement may not be uniform)

Indiana (enforcement may not be uniform)

Kentucky (enforcement may not be uniform)

Minnesota

Missouri

New Hampshire

New Jersey

Montana (legal, but not in bordering states)

New Mexico (not from licensed medical dispensaries)

New York (but not as an additive to food or beverages)

North Carolina (but not as an additive to food, beverages or supplements)

Oklahoma (at dispensaries with a food license for consumables)

Pennsylvania (for hemp-derived product; marijuana-derived CBD must go through the state's medical cannabis system)

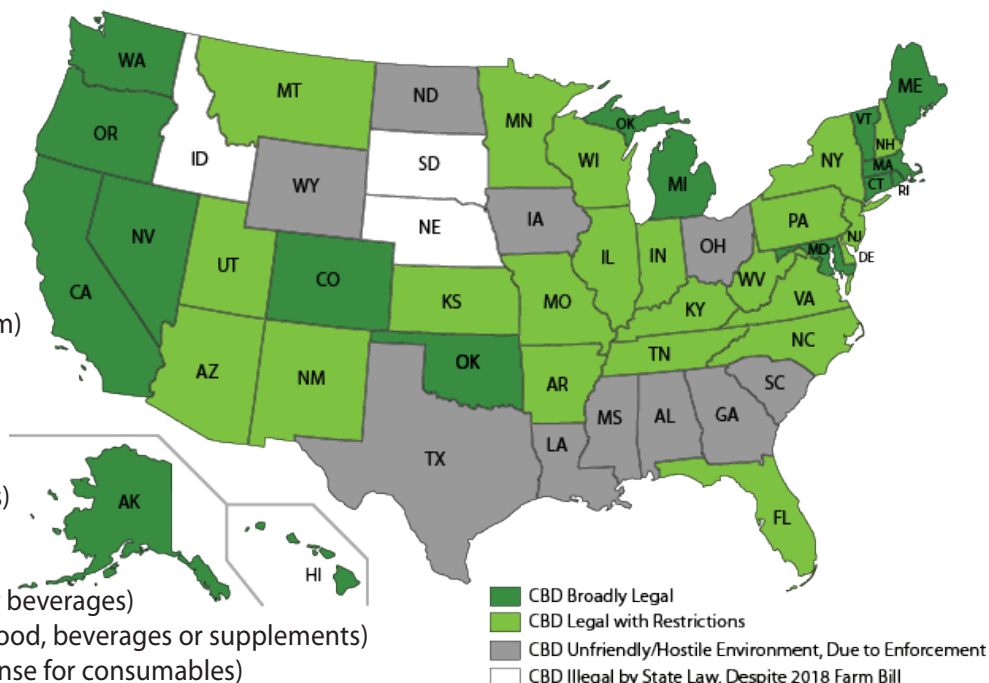
Tennessee (for now, only with 0% THC)

Utah (for both CBD oil and hemp products, if products are state-registered, with samples for quality testing provided to the state)

Virginia (only within their medical cannabis program)

West Virginia (enforcement may not be uniform)

Wisconsin (as of 2018, only in certain circumstances and with a doctor's approval; but in 2019, sold in stores in some cities)



### Broadly Legal:

Alaska, California, Colorado, Connecticut, Hawaii, Maine, Maryland, Massachusetts, Michigan, Nevada, Oregon, Rhode Island, Vermont, Washington, Washington, D.C.

## What are the Most Important Facts for CBD Product Labelers to Know?

Manufacturers and distributors of CBD-containing goods who are labeling their products must answer all the usual questions, such as: "How do I create a label with a **good logo design**?" and "How do I use my **label to help market my product** successfully?" But CBD labelers and providers also have to comply with a confusing and constantly shifting set of regulations, without adequate or clear federal guidelines.

**Get Your Free CBD Product Label Quote**

# What Do You Need to Know For an FDA-Compliant CBD Product Label?

Starting as of February, 2019, the FDA has been cracking down on CBD uses that are illegal under their current regulations. Having legalized CBD-derived Epidiolex, a medicine for epilepsy, the FDA now holds that CBD in general is a drug. They are also concerned because CBD products have been sold without any regulation, so the quality varies widely. A study from the University of Pennsylvania School of Medicine found that nearly 7 in 10 of CBD products did not contain the amount of extract promised on the label. Nearly 43% of products contained too little, and 26% contained too much: EurekaAlert Publication.<sup>7</sup>

The FDA's current position is that CBD cannot be added to food, sold as a nutritional supplement, or labeled with unapproved health claims. Since February 11, 2019, state regulators have been sending out warning letters, which apply to both interstate and intrastate commerce, to advise companies identified as violating state and federal CBD laws. The warning letters state that "prohibited acts" include:

- Adding CBD to food products and beverages
- Making unregulated or "unsubstantiated" health claims about CBD
- Selling CBD in nutritional supplements

The immediate strategy of the FDA is simply to advise companies of the law, not to penalize or fine them, but this could change at any point. Currently, inspectors will document when businesses sell CBD-containing products to determine if they are in compliance. States such as California, Georgia and North Carolina have moved to comply with FDA regulations. Cities, such as New York City, have also sided with federal authorities. New York City health inspectors, for example, have begun to confiscate CBD-infused cookies and other baked goods.<sup>8</sup>

In response, a number of companies have changed the language of their hemp-CBD infused nutritional product labels and advertising, choosing to offer products with hemp extracts standardized for total cannabinoid content rather than isolated CBD. But note that the term "hemp extract" would not necessarily protect a company from an FDA enforcement action if the CBD concentrations in a dietary supplement are shown to be out of proportion to the levels that would be found naturally in a plant or in a traditional hemp extract.

## How Can A Company Best Comply With FDA Product Labeling Regulations?

In an environment without firm legal guidelines, extreme caution could be the best approach for any company. Retaining legal counsel familiar with CBD/hemp/cannabis law is strongly recommended, as is performing due diligence by reviewing studies impacting the legality of CBD products and their labels. During this waiting period, for those companies selling a topical product, the FDA's rules for labeling cosmetics will have to serve as the best set of references.<sup>9</sup>

In marketing, labeling and selling your products, it is advisable to avoid making any health claims about their benefits. At this stage, whether or not you believe that your products are anti-inflammatory, relieve headaches, act as a sleeping aid, or promote brain health, be careful about including copy to that effect on your product labels or in your advertising, including your digital ads: Regulations for CBD product labeling.<sup>10</sup>

It may be safer to take an approach similar to that of many companies selling herbal preparations or nutritional supplements in pill, liquid or capsule form; their labels offer no actual health claims. These are the types of labels that often include an FDA disclaimer "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."





# What Do You Need to Know For an FDA-Compliant CBD Product Label?

Following the FDA regulations for cosmetic product labeling, CBD-infused cosmetic product labels most importantly should:

- Not be false or misleading
- Not violate the Poison Prevention Packaging Act of 1970
- Provide required information including:
  - An **Identity Statement**, e.g., “hemp extract” or “herbal extract”
  - A **Net Quantity of Contents Statement**, expressed as net weight (volume of the container for liquids)
  - A **Name and Place of Business Statement** of the firm marketing the product, including street address, city, state, and zip code. If the firm is listed in a telephone directory, the street address may be omitted. If the distributor is not the manufacturer or packer, this fact must be stated on the label by the qualifying phrase “Manufactured for\_\_\_\_\_” or “Distributed by\_\_\_\_\_” or similar, appropriate wording. All imported articles must state on the label the English name of the country of origin
  - **Material Facts** (important information that might affect a decision in a court of law)
  - **Warning or Caution Statements**
  - An **Ingredient Statement** – all of the product’s ingredients, listed in descending order of their presence, based on the weight of the product. With a CBD product label, you must identify the parts of the hemp plant used

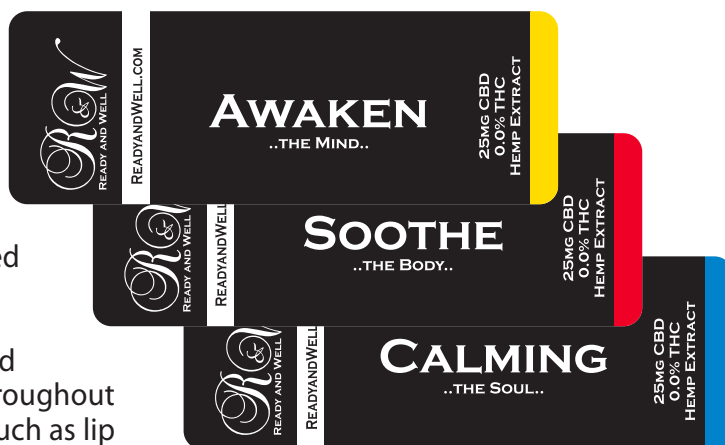
The most important part of labeling, the one most often done incorrectly, is the front of the package (known as the **Principal Display Panel** or **PDP**.) The PDP is that part of the label that is most likely to be shown or examined under customary conditions for retail sale. This panel, by law, must include certain vital pieces of the above-listed information. The declaration must be distinct, placed in the bottom area of the panel, and in a line generally parallel to the base on which the package rests. It must appear in a type size commensurate with the size of the container as prescribed by regulation. **PDP** information that must be included consists of:

- The name of the product
- The accurate statement of the net weight, (volume of the container for liquids,) measure or numerical count
- The statement of identity: for example, “hemp extract” or “herbal extract”
- The identity of the parts of the hemp plant used, and an indication of the total amount of hemp extract or oil (in milligrams)

## What Types of CBD Products are Still Federally Legal for Sale?

Tinctures of CBD oil, that is, concentrated liquid herbal extract not considered a nutritional supplement or food, remain legal because they fall outside of existing laws and regulations. The FDA has not provided any regulatory guidance on these products. Other compounds, including hulled hemp seeds, hemp seed protein, and hemp seed oil, were classified in December of 2018 as Generally Recognized as Safe (GRAS) and are still allowed.

This means that topical products that contain liquid or dried preparations of CBD oil are still legal at the Federal level throughout the U.S. Products that will be applied to the skin and hair, such as lip balm, bath salts, deodorants, scrubs, face creams and serums, shampoos, body oils and body lotions containing CBD oil, are legal as well.



# What Do You Need to Know For an FDA-Compliant CBD Product Label?

## What is the Status of CBD Going Forward?

Due to the lack of large, controlled human trials, most physicians and scientists do not support the bulk of health claims for CBD. Only one CBD-derived drug, Epidiolex, used to treat two forms of a rare childhood epilepsy, is FDA approved. The FDA held a public hearing in May of 2019, and was originally planning to issue updated guidelines by the end of summer 2019, but the ultimate report could take another 12-to-18 months to issue.

Meanwhile, agricultural research and development for better medical CBD products continues. Kentucky farmers are purchasing specially bred, low-THC marijuana plant clones from North Carolina to grow back home. These plants come with all of the other trace cannabinoids, terpenes and flavonoids, for a full-spectrum, "entourage effect".<sup>11</sup> These plant clones are being referred to as "medical" rather than "industrial" hemp. And in Colorado, farmers are picking marijuana plants early to have less than 0.3% of THC, calling them "hemp," and using them to extract full-spectrum CBD oil.

The National Institutes of Health keeps a database of over 150 international clinical trials for CBD, some still recruiting test subjects. For example, an Australian study<sup>12</sup> is testing CBD as an antimicrobial against drug-resistant bacterial strains and the New York University School of Medicine is investigating CBD to treat alcohol use disorder.<sup>13</sup>

The World Health Organization concluded in a press release that CBD is not harmful. And in the sports industry, the World Anti-Doping Agency removed it from its prohibited substances list.

## Summary

In the current regulatory climate, the best approach for any company hoping to break into and/or thrive in the CBD market is a combination of knowledge and patience. It is important to work with experts, including legal counsel, familiar with the laws governing the labeling and sale of CBD products, and to know which products are currently legal for sales. Until the FDA gives the go-ahead for wide-spread usage of CBD oils, the legality of many products will remain uncertain and consumer confidence may wane for some period of time. Therefore, it is especially important to cultivate the willingness to be patient with the FDA's decision-making process for the legality of hemp and its derived products. The rewards could prove to be well worth the wait.

If you are thinking about creating a label for your CBD product, you can rely on our knowledge and expertise. Contact us today to discuss your labeling needs and how we can help you!

*\*SixB Labels Corporation provides this quick reference for our clients and is not responsible for any errors. Please direct all questions to [www.FDA.gov](http://www.FDA.gov)*

SixB Labels excels in producing effective Product Labels, so let us put our resources to work for you. If you are planning to change your current Product Labels or create new ones, call us for a consultation!

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# What Do You Need to Know For an FDA-Compliant CBD Product Label?

## Appendix

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