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# **CANNABIS & HEMP CONFERENCE**

**OCTOBER 24-25, 2019 | MARRIOTT MARQUIS | NEW YORK CITY**

**Clear as Mud: The 2018  
Farm Bill, the FDA and the  
Uncertainty of Entering  
the Hemp Space**



# Hemp or Marijuana?



Photo credit: Greenbrier Hemp



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# THE TUG-O-WAR OVER HEMP



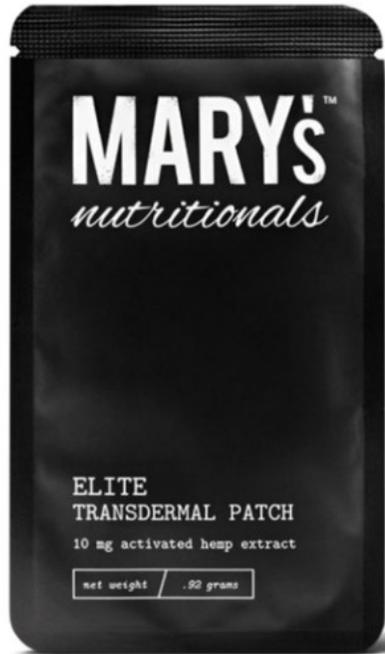
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# CBD Marketing and Labeling



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# FDA Warning Letters – Curaleaf (July 22, 2019)

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address <https://curaleafhemp.com> in April and June 2019 and has determined that you take orders there for the products “CBD Lotion,” “CBD Pain-Relief Patch,” “CBD Tincture” (5 versions), “CBD Disposable Vape Pen” (5 versions) and “Bido CBD for Pets” (3 versions), all of which you promote as products containing cannabidiol (CBD). We have also reviewed your social media websites at [www.facebook.com/CuraleafHemp](http://www.facebook.com/CuraleafHemp) and <https://twitter.com/curaleafhemp>; these websites direct consumers to your website, <https://curaleafhemp.com>, to purchase your products. FDA has determined that your “CBD Lotion,” “CBD Pain-Relief Patch,” “CBD Tincture,” and “CBD Disposable Vape Pen” products are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 355(a) and 331(d). Furthermore, these products are misbranded drugs under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1). FDA has also determined that your “Bido CBD for Pets” products are unapproved new animal drugs that are unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. 351(a)(5). As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the FD&C Act. You can find the FD&C Act and FDA regulations through links on FDA’s home page at [www.fda.gov](http://www.fda.gov).

## On your webpage titled “CBD Benefits: Top 5 Research-Backed Benefits of CBD”

- “CBD has also been shown to be effective in treating Parkinson’s disease.”
- “CBD has been linked to the effective treatment of Alzheimer’s disease . . . .”
- “CBD is being adopted more and more as a natural alternative to pharmaceutical-grade treatments for depression and anxiety.”
- “CBD can also be used in conjunction with opioid medications, and a number of studies have demonstrated that CBD can in fact reduce the severity of opioid-related withdrawal and lessen the buildup of tolerance.”
- “CBD has been demonstrated to have properties that counteract the growth of spread of cancer.”
- “CBD was effective in killing human breast cancer cells.”

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# FDA Warning Letters – Rooted Apothecary LLC (October 10, 2019)

## Dietary Supplement Labeling

In addition, information on your website and social media account indicates that you market your “Hemp Capsules, 750 mg” and “Hemp Oil” products as dietary supplements that contain CBD. However, these products cannot be dietary supplements, because they do not meet the definition of a dietary supplement under section 201(ff) of the FD&C Act, 21 U.S.C. 321(ff). FDA has concluded that, based on available evidence, CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, 21 U.S.C. 321(ff)(3)(B)(i) and (ii). Under those provisions, if an article (such as CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act, 21 U.S.C. 355, or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that article are outside the definition of a dietary supplement. There is an exception if the substance was “marketed as” a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on the evidence available, FDA has concluded that this is not the case for CBD.<sup>[3]</sup> FDA is not aware of any evidence that would call into question its current conclusion that CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, but you may present FDA with any evidence that has bearing on this issue.<sup>[4]</sup>



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# FTC Warning Letters (September 10, 2019)

As part of its regular monitoring of health-related advertising claims, the Federal Trade Commission today sent warning letters to three companies that sell oils, tinctures, capsules, “gummies,” and creams containing cannabidiol (CBD), a chemical compound derived from the cannabis plant. The letters warn the companies, which the FTC is not identifying publicly, that it is illegal to advertise that a product can prevent, treat, or cure human disease without competent and reliable scientific evidence to support such claims.

Each company has advertised that its CBD products treat or cure serious diseases and health conditions. One company’s website claims CBD “works like magic” to relieve “even the most agonizing pain” better than prescription opioid painkillers. To bolster its claims that CBD has been “clinically proven” to treat cancer, Alzheimer’s disease, multiple sclerosis (MS), fibromyalgia, cigarette addiction, and colitis, the company states it has participated in “thousands of hours of research” with Harvard researchers.

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# CBD Class Action Litigation

## Thurston v. Koi CBD, LLC (LA County Sup. Court)

### NATURE OF THE CASE

1. This is an action seeking damages, declaratory and injunctive relief to restrain KOI from marketing cannabidiol (“CBD”) products (the “Products”)<sup>1</sup> as drugs, purportedly able to treat a wide array of diseases and conditions, including cancer and its side effects; depression and post-traumatic stress disorder (“PTSD”); chronic pain; arthritis and other inflammation-related diseases; migraines; heart disease, asthma; liver disease; glaucoma; and epilepsy, all without the required pre-approval of the U.S. Food and Drug Administration (“FDA”) as being safe and effective for these marketed purposes.

43. Linking or reposting consumer testimonials is an adoption of the testimonial for a company’s own product. See 16 C.F.R. § 255.2(a). When a testimonial concerns a person’s health, FDA considers such claim to be part of the product’s labeling in determining whether it is being advertised to treat any condition or disease.<sup>19</sup>

### TESTIMONIALS

#### HEAR HOW KOI CBD PRODUCTS HAVE HELPED PEOPLE JUST LIKE YOU.

This is why we created Koi CBD. It's the stories of how Koi products have helped our customers live fuller, more productive lives that gets us out of bed and excited to go to work every day.

Want to see what CBD can do for you? Click on a category below to read the testimonials of people who have already experienced the transformative power of Koi CBD.



CBD Success Stories about Anxiety

Read More



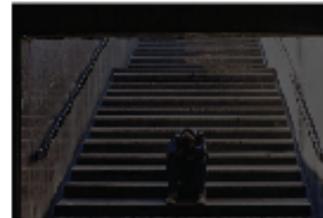
CBD Success Stories About Chronic Pain

Read More



CBD Success Stories about Arthritis & Fibromyalgia

Read More



CBD Success Stories About Depression

Read More



CBD Success Stories about Post-Traumatic Stress Disorder

Read More



CBD Success Stories about Migraines

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# CBD Class Action Litigation

## Snyder v. Green Roads of Florida (S.D. Fla.)

16. Yet, as reflected in the image below, the package and label of the 250 mg version of Green Roads' CBD Oil both prominently claim a CBD level of 17 mg per ml—even though that amount is materially inaccurate.



## Potter v. Potnetwork Holdings, Inc. (S.D. Fla.)

16. As reflected in the image below, the package and label of the 550 mg version of Diamond CBD's CBD Oil both prominently claim a CBD level of 550 mg per fl. oz.—even though that amount is materially inaccurate.



## Ahumada v. Hemp Bombs (D. Mass)

48. Contrary to Defendant's uniform representation of the dosage of CBD on the Products' labels, plaintiff-commissioned laboratory testing shows that the Products are in fact grossly underdosed.



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# CBD Class Action Litigation

## Gaddis v. Just Brands US, Inc. (S.D. Fla.)

17. Notwithstanding that business philosophy, Defendants' CBD Claims are false and misleading. As independent lab testing reveals, the true quantity of CBD in the CBD Products is only a small fraction of Defendants' representations. Plaintiff's counsel commissioned Anresco Laboratories to perform independent testing of Defendants' products, which show that the Products do not contain the amount of CBD promised in the CBD Claims. Specifically, pursuant



## Skibbe v. Curaleaf Holdings, Inc. (E.D.N.Y.)

35. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

*High-quality CBD pet drops and soft-baked bites support a pet's overall health*

WAKEFIELD, Mass., May 10, 2019 /PRNewswire/ -- [Curaleaf Holdings, Inc.](#) (CSE: CURA) (OTCQX: CURLF) ("Curaleaf"), a leading vertically integrated cannabis operator in the United States, today announced the launch of Bido, hemp-based CBD products for pets. CBD is a non-intoxicating, non-psychoactive compound from the cannabis sativa plant. ***CBD has been shown in initial third-party studies to support a pet's overall wellness including the potential to help manage pain and anxiety.*** Bido pet drops come in three varieties, bacon, salmon and unflavored "pure," and Bido soft-baked bites are available in apple chicken, peanut butter bacon, and honey sweet potato. All Bido products can be purchased online at [www.curaleafhemp.com](http://www.curaleafhemp.com).

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# Vaping Epidemic

**CDC** Centers for Disease Control and Prevention  
CDC 24/7: Saving Lives, Protecting People™

**New York State Department of Health Announces Update on Investigation into Vaping-Associated Pulmonary Illnesses**

**Department Warns Against Use of Black Market Vaping Products**

**Lab Test Results Show High Levels of Vitamin E Acetate, Now Focus of Investigation**

## Symptoms of Lung Injury Reported by Some Patients in This Outbreak

- Patients in this investigation have reported symptoms such as:
  - cough, shortness of breath, or chest pain
  - nausea, vomiting, or diarrhea
  - fatigue, fever, or abdominal pain
- Some patients have reported that their symptoms developed over a few days, while others have reported that their symptoms developed over several weeks. A lung infection does not appear to be causing the symptoms.



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# State Regulation and Best Practices



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