

## Report to the Boards of Health

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### **CBD Oil**

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The plant *Cannabis sativa* contains over 500 distinct compounds in classifications such as cannabinoids, terpenoids, flavonoids, and omega fatty acids. There have been over 100 different cannabinoids identified, the most well-known are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is responsible for the “high” and addictive properties of cannabis, whereas CBD does not appear to produce these effects. There is evidence that CBD can help some health issues. For example, it has been found to help two severe childhood epilepsy conditions, Dravet syndrome and Lennox-Gastaut syndrome which usually do not respond to traditional antiseizure medications. In 2018, the U.S. Food and Drug Administration (FDA) approved Epidiolex, a CBD medication to treat these two forms of epilepsy. In addition, there is evidence suggesting CBD has antioxidant, anti-inflammatory, pain relieving, and anti-anxiety properties. Because of this, CBD has been promoted for use to treat many illnesses, including Parkinson’s disease, schizophrenia, drug addiction, anxiety, insomnia, multiple sclerosis, chronic pain, and cancer. It is also used to prevent illness despite lack of evidence for many of these claims.

CBD is now available at for sale at countless stores and on-line and is available in many different forms, most commonly as an oil. The CBD in these oils and other products is typically produced from hemp. Under current U.S. federal law, *C. sativa* is legally divided into two distinct varieties: hemp and marijuana. Hemp is *C. sativa* that has levels of THC that is not over 0.3% of its dry weight as now established in section 297A of the Agricultural Marketing Act of 1946 as amended by the 2018 Farm Bill. Marijuana is *C. sativa* that cannot be defined as hemp as described above, in other words, has THC levels of 0.3% or more. Of note, other countries have different definitions of hemp: in the European Union hemp cannot have THC over 0.2%, in Switzerland THC can be as high as 1%, and in the Netherlands any detectable amount of THC in hemp is illegal. Because different countries have different laws and allow different activities, hemp production often spans multiple countries to bypass regulations.

In general, CBD oil is considered safe, though there is very little known about the long term effects of CBD. Epidiolex, which is pure CBD plus trivial amounts of inactive ingredients (sesame oil, strawberry flavor, and dehydrated alcohol), was studied heavily in properly conducted trials and the most common side effects were found to be: drowsiness (in up to 30%), decreased appetite (in 16 to 22%), diarrhea (in 9 to 20%), weight loss (in 3 to 18%), anemia (in 30%), significantly abnormal liver function tests (in 13 to 17%), and infections (in 25 to 41%). Epidiolex also inhibits drug metabolism by the enzyme CYP2C19, which could cause increased levels of numerous commonly used drugs such as antidepressants, antipsychotics, methadone, and blood thinners.

Currently, the biggest risk with CBD products is the lack of quality control and consistency in the products available. Contaminants such as pesticides, metal particles, synthetic cannabinoids, molds, bacteria, solvents, THC, and others have all been found in CBD products. Testing of numerous CBD products from the U.S. and other countries has repeatedly found the CBD content is not as labeled, and many contained THC when labeled as THC free. Some products contained enough THC to cause intoxication or a “high”, especially if given to a child. There is also no general agreement on how to best analyze the concentration of CBD and other cannabinoid products and there are no guidelines or certifications to determine if a cannabis testing lab is qualified.

The legality of CBD products in general, per the FDA, is still not clear. The 2018 Farm Bill included a provision identified as the Hemp Farming Act. States were allowed to have primary regulatory authority over hemp production, otherwise they would have to comply with the USDA’s plan. In Michigan, growing industrial hemp will require a license from the Michigan Department of Agriculture and Rural Development (MDARD). MDARD is in the process of developing a licensing program for growers to meet the requirements of both state and federal laws to allow interstate commerce of the plants. MDARD launched an Industrial Hemp Ag Pilot Program in April 2019. According to the State of Michigan ([https://www.michigan.gov/documents/lara/2019-lara-marijuana-hemp-handout-2-PAGE-APPROVED\\_664370\\_7.pdf](https://www.michigan.gov/documents/lara/2019-lara-marijuana-hemp-handout-2-PAGE-APPROVED_664370_7.pdf)) “Products derived from industrial hemp, including CBD oil, fall under several different categories. Any substances that will be added to food, drink, animal feed, or marketed as

dietary supplements must first be approved by the U.S. Food and Drug Administration for that intended use. **At this time, the FDA has not approved CBD for use in food, drink, animal feed or as a dietary supplement. Therefore, it's currently illegal to add CBD into food, animal feed products or drinks or dietary supplements.** GRAS (Generally Regarded As Safe) is a list of substances that the FDA considers safe to add to food or animal feed. **While hulled hemp seeds, hemp seed protein and hemp seed oil are considered GRAS for human food, these products are currently not considered GRAS in animal feed and are not approved to be added as an ingredient in animal feed. CBD is currently not considered GRAS, as of 4/18/19."**

According to the American Herbal Products Association (AHPA), because CBD is a constituent of hemp, which is "an herb or other botanical," CBD meets the definition of a dietary ingredient under 21 U.S.C. § 321 and should be allowed as an ingredient in a dietary supplement. The FDA, however, currently cites a provision of the FDCA (21 U.S.C. §321) that excludes from the definition of "dietary supplement" any "article" that has been approved as a new drug or authorized for investigation as a new drug in conjunction with certain other conditions. In supporting this argument, the FDA has specifically cited announcements issued by GW Pharmaceuticals with regard to its Cannabis-derived drugs Sativex® ("an investigational new product composed primarily of two cannabinoids: CBD ... and THC;" press release issued November 26, 2007) and Epidiolex® (identified as "a prescription cannabidiol (CBD) medicine;" press release issued May 7, 2014). FDA has stated its belief that CBD was marketed as a dietary supplement prior to the announcements of its authorization of investigations of these CBD drug products. FDA has taken the same position with regard to CBD as an ingredient in conventional food, citing a separate but similar section of the FDCA that prohibits the addition of a drug to a food unless the drug was marketed in food before the drug's approval or any substantial clinical investigations involving the drug were instituted (21 U.S.C. § 331(II)).

In terms of enforcement, the FDA has sent warning letters to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were also violating the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food. The FDA has taken no other action. Marketers of CBD and legal experts believe that FDA's interpretations of these provisions are inaccurate.

### Recommendations

1. While CBD may be safe and could have medical benefits, the over-the-counter products available today should be avoided at this time as they are unregulated, often contaminated, and often do not contain the CBD and THC concentrations as labeled.
2. If you do choose to use CBD products, do your best to purchase from a reputable company. Though testing of CBD and other cannabinoid products is still evolving, third party agencies such as NSF and USP will soon begin testing and certifying CBD products. The U.S. Hemp Authority (<https://www.ushempauthority.org/certified-companies>), an initiative by hemp growers, has already been testing and certifying hemp and hemp products.

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