



Questions and Answers about Cannabis-Derived Products, Including CBD

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1. What is the difference between cannabis, hemp and industrial hemp?

Cannabis is a family of plants with two main species—indica and sativa. Cannabis contains a variety of compounds called cannabinoids. THC (delta-9-tetrahydrocannabinol) and CBD (cannabidiol) are usually the most common cannabinoids in cannabis. THC causes a psychoactive effect (or a “high”), while CBD does not contain psychoactive properties.

Hemp is cannabis that contains a very low concentration of THC (0.3 percent or less). Plants that contain more than 0.3 percent THC are considered cannabis, also sometimes known as marijuana. Industrial hemp is hemp that is high in fiber grown for industrial purposes, such as to make rope, textiles, paper, and many other products. Hemp seeds (and the oil from the seeds) are used as a food source. To grow hemp in Hawaii, you must have a license from the Hawaii Department of Agriculture. For more on Hawaii’s Industrial Hemp Pilot Program, visit <http://hdoa.hawaii.gov/hemp/hemp-faqs/>.

2. What is CBD?

CBD (cannabidiol) is one of the two main compounds found in cannabis. It does not have psychoactive properties and doesn't make a person feel high. CBD is one type of cannabis-derived product.

3. How are cannabis-derived products and CBD regulated under federal law?

The Agriculture Improvement Act of 2018 was signed into law on December 20, 2018, and removed hemp from the Controlled Substances Act. Under this law, cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law.

However, the 2018 Farm Bill explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act (PHS Act). FDA treats products containing cannabis or cannabis-derived compounds as any other FDA-regulated products – meaning they are subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of whether the cannabis or cannabis-derived compounds are classified as hemp under the 2018 Farm Bill.

4. How are cannabis-derived products, including CBD, regulated in Hawaii?

The Hawaii Department of Health (DOH) regulates all cannabis-derived products (regardless of whether they are derived from hemp) consistent with FDA's approach. These products are not considered safe and may have potential health risks.

DOH is concerned about the growing number of products available to the public that contain CBD. Because CBD is an active ingredient in an FDA-approved prescription drug, it cannot be sold without a valid prescription or over the counter.

In addition, selling products that make unproven health claims is a violation of Hawaii law and is considered "misbranding" or "false advertising" as defined in HRS Chapter 328. False advertising places everyone at risk because people may not be aware that a product has not been proven to be safe or effective. Unfortunately, patients who are suffering from serious illness or potentially fatal diseases may want to believe product claims and choose to use these products instead of appropriate and effective therapies.

5. Can CBD be sold as a dietary supplement?

No. CBD may not be sold as a "dietary supplement." CBD is an active ingredient in an FDA-approved prescription drug.

6. Can CBD be added to food, beverages or cosmetics that are distributed and sold in Hawaii?

No. Chapter 328 of the Hawaii Revised Statutes (HRS) prohibits the manufacture, distribution and sale of food products and cosmetics made with cannabis, or products intended for consumption containing CBD or use of CBD as a food additive. Neither FDA nor DOH recognize cannabis-derived products, including CBD, as safe, nor have they been approved as a food additive. Cannabis-derived products, including CBD, are considered adulterated.

7. When did it become illegal to add CBD to food, beverages or cosmetics?

CBD has never been approved as an ingredient to be used in food, beverages or cosmetics in Hawaii. CBD may not be added to food, beverages or cosmetics, sold without a prescription, or marketed as a “dietary supplement.”

8. Does this affect CBD products manufactured and sold by Hawaii’s licensed medical cannabis dispensaries?

No. Licensed medical cannabis dispensaries may legally produce and sell products containing THC and CBD. They are allowed to do so under HRS Chapter 329-D and the strict regulatory oversight of DOH.

Medical cannabis cardholders may continue to purchase products containing THC and CBD through licensed dispensaries in Hawaii including capsules; lozenges; pills; oils and oil extracts; tinctures; ointments and skin lotions; transdermal patches; and pre-filled and sealed containers used to aerosolize and deliver cannabis orally.

9. Are there any FDA-approved uses of CBD?

Yes. Epidiolex is the only FDA-approved drug containing CBD and is available only by prescription from a licensed healthcare provider. Epidiolex is considered safe and effective as a prescribed FDA-approved treatment for seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.

10. Is any part of hemp considered safe enough to add to food?

Yes. In December 2018, the FDA announced generally recognized as safe (GRAS) notices for three hemp seed-derived food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil. Only these three products can be legally marketed in human foods for the uses described in the notices, provided they comply with all other requirements.

11. What are potential health risks associated with cannabis-derived products, including CBD?

Because over-the-counter CBD products are not legally manufactured, these products may be unsafe and may have potential health risks. Consumers should be aware that over-the-counter CBD products may contain more, or less, CBD than labeled, or be tainted with contaminants.

Information based on proven scientific evidence about products made from cannabis is limited. Hawaii, like many other states, is proactively taking steps to protect people’s health, especially until we know more about the risks and benefits of cannabis-derived products, including CBD.

a. Issues with contaminants, concentration rates, and synthetics

A survey of 84 CBD products from 31 companies¹ found that 26 percent contained less CBD than labeled, 43 percent contained more CBD than labeled, and THC was detected in 21 percent at levels sufficient to produce intoxication or impairment, especially among children. Another survey of seven over-the-counter CBD products² found that four contained a synthetic cannabinoid and one contained, dextromethorphan, a chemical generally found in cough syrup.

¹ <https://jamanetwork.com/journals/jama/fullarticle/2661569>

² <https://www.sciencedirect.com/science/article/pii/S0379073818307047?via%3Dihub>

Negative health impacts associated with CBD products have also been reported. For example, from December 2017-January 2018, 52 persons in Utah experienced adverse reactions including altered mental status, seizures, confusion, loss of consciousness, and hallucinations after using products labeled as CBD or hemp oil. After testing, the products were found to be tainted with a synthetic cannabinoid. Synthetic cannabinoids were also associated with 153 illnesses and four deaths in Illinois in 2018.

Since 2015, FDA has issued nearly 50 warning letters to firms marketing products that allegedly contain CBD and found that many did not contain the levels of CBD they claimed to contain.³ FDA warns consumers that CBD products are not approved by FDA for the diagnosis, cure, mitigation, treatment, or prevention of any disease.

b. Negative side-effects of CBD

MedlinePlus⁴ notes that CBD, is possibly safe but reported side effects include dry mouth, low blood pressure, light headedness, and drowsiness. Signs of liver injury have also been reported in some patients, but this is less common. Side effects and drug interactions were also identified by the FDA during the clinical trials of Epidiolex (purified CBD)⁵. Epidiolex has been shown to interact with certain prescription medications and can therefore either enhance or reduce the effects of these medications.

c. Risks of using CBD as an alternative to doctor-prescribed medication

Using over-the-counter CBD products as a substitute for medication prescribed by a physician is potentially risky because patients may be replacing medication proven to be safe and effective. There is also a risk that using CBD with other prescription drugs can result in interactions that make the prescribed drugs ineffective or create unforeseen and possibly harmful side effects. Consumers should consult their physician for the most effective treatments and beware of drugs not approved by the FDA.

12. What can people do if they experience adverse health effects from CBD use?

The public should be aware of the possible side effects of CBD use. If harmful symptoms arise, call the Hawaii Poison Hotline at 1 (800) 222-1222 and seek medical attention.

13. Are cannabis-derived products, including CBD, safe for pets?

FDA has not approved cannabis-derived products, including CBD, for any use in products for animals. FDA cautions pet-owners against the use of such products and recommends that you talk with your veterinarian about appropriate treatment options for your pet.

Signs that your pet may be suffering adverse effects from ingesting cannabis may include lethargy, depression, heavy drooling, vomiting, agitation, tremors, and convulsions.

If you have concerns that your pet is suffering adverse effects from ingesting cannabis or any substance containing cannabis, consult your veterinarian, local animal emergency hospital or an animal poison control center immediately.

³ <https://www.fda.gov/newsevents/publichealthfocus/ucm484109.htm>

⁴ <https://medlineplus.gov/druginfo/natural/1439.html#Safety>

⁵ <https://www.fda.gov/Drugs/InformationOnDrugs/ucm613357.htm>

14. How can I provide comments on FDA's rules regarding cannabis-derived products?

A public hearing will be held by the FDA on May 31, 2019, from 8 a.m. to 6 p.m. to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling and sale of products containing cannabis or cannabis-derived compounds. The public may attend in person or submit either electronic or written comments on this public hearing by July 2, 2019.

For more information and instructions on how to submit comments, visit <https://www.federalregister.gov/documents/2019/04/03/2019-06436/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds>.

15. Where can I get more information?

The FDA has been providing regular updates on its website and keeps its frequently asked questions posted at <https://www.fda.gov/newsevents/publichealthfocus/ucm421168.htm>.

Health information is evolving rapidly. DOH will provide updates to the public on its Food & Drug Branch website at <http://health.hawaii.gov/food-drug/>.

Permitted food establishments should contact DOH's Sanitation Branch using information posted at <http://health.hawaii.gov/san/contact-us/>.

Other retailers selling products containing CBD as well as members of the public with general inquiries should contact DOH's Food & Drug Branch by email at doh.fdbinfo@doh.hawaii.gov.

Farmers or others in the agricultural industry should contact the Hawaii Department of Agriculture's Industrial Hemp Pilot Program by email at hemp@hawaii.gov.

*****Note: This content was last updated on Friday, April 26, 2019, and is subject to change as new information becomes available.**