

# State of Louisiana

Office of Alcohol and Tobacco Control

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## FDA CBD NEED TO KNOW NOTICE

### **What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD:**

The FDA is working to answer questions about the science, safety, and quality of products containing cannabis and cannabis-derived compounds, particularly CBD.

- The FDA has approved only one CBD product, a prescription drug product to treat two rare, severe forms of epilepsy.
  - It is currently illegal to market CBD by adding it to a food or labeling it as a dietary supplement.
  - The FDA has seen only limited data about CBD safety and these data point to real risks that need to be considered before taking CBD for any reason.
  - Some CBD products are being marketed with unproven medical claims and are of unknown quality.
  - The FDA will continue to update the public as it learns more about CBD.
1. CBD has the potential to harm you, and harm can happen even before you become aware of it.
    - a. CBD can cause liver injury.
    - b. CBD can affect the metabolism of other drugs, causing serious side effects.
    - c. Use of CBD with alcohol or other Central Nervous System depressants increases the risk of sedation and drowsiness, which can lead to injuries.
  2. CBD can cause side effects that you might notice. These side effects should improve when CBD is stopped or when the amount ingested is reduced.
    - a. Changes in alertness, most commonly experienced as somnolence (drowsiness or sleepiness).
    - b. Gastrointestinal distress, most commonly experienced as diarrhea and/or decreased appetite.
    - c. Changes in mood, most commonly experienced as irritability and agitation.
  3. There are many important aspects about CBD that we just don't know, such as:
    - a. What happens if you take CBD daily for sustained periods of time?
    - b. What is the effect of CBD on the developing brain (such as children who take CBD)?
    - c. What are the effects of CBD on the developing fetus or breastfed newborn?
    - d. How does CBD interact with herbs and botanicals?
    - e. Does CBD cause male reproductive toxicity in humans, as has been reported in studies of animals?

You may have noticed that cannabidiol (CBD) seems to be available almost everywhere, and marketed as a variety of products including drugs, food, dietary supplements, cosmetics, and animal health products. Other than one prescription drug product to treat two rare, severe forms of epilepsy, the U.S. Food and Drug Administration (FDA) has not approved any other CBD products, and there is very limited available information about CBD, including about its effects on the body.

The FDA recognizes the significant public interest in cannabis and cannabis-derived compounds, particularly CBD. However, there are many unanswered questions about the science, safety, and quality of products containing CBD. The agency is working on answering these questions through ongoing efforts including feedback from a recent FDA hearing and information and data gathering through a public docket.

Despite the 2018 Farm Bill removing hemp — defined as cannabis and cannabis derivatives with very low concentrations (no more than 0.3% on a dry weight basis) of THC — from the definition of marijuana in the Controlled Substances Act, CBD products are still subject to the same laws and requirements as FDA-regulated products that contain any other substance.

The FDA is concerned that people may mistakenly believe that trying CBD “can’t hurt.” The agency wants to be clear that we have seen only limited data about CBD’s safety and these data point to real risks that need to be considered. As part of the drug review and approval process for the prescription drug containing CBD, it was determined that the risks are outweighed by the benefits of the approved drug for the particular population for which it was intended. Consumer use of any CBD products should always be discussed with a healthcare provider. Consumers should be aware of the potential risks associated with using CBD products. Some of these can occur without your awareness, such as:

**Liver Injury:** During its review of the marketing application for Epidiolex — a purified form of CBD that the FDA approved in 2018 for use in the treatment of two rare and severe seizure disorders — the FDA identified certain safety risks, including the potential for liver injury. This serious risk can be managed when an FDA-approved CBD drug product is taken under medical supervision, but it is less clear how it might be managed when CBD is used far more widely, without medical supervision, and not in accordance with FDA-approved labeling. Although this risk was increased when taken with other drugs that impact the liver, signs of liver injury were seen also in patients not on those drugs. The occurrence of this liver injury was identified through blood tests, as is often the case with early problems with the liver. Liver injury was also seen in other studies of CBD in published literature. We are concerned about potential liver injury associated with CBD use that could go undetected if not monitored by a healthcare provider.

**Drug Interactions:** Information from studies of the FDA-approved CBD drug Epidiolex show that there is a risk of CBD impacting other medicines you take – or that other medicines you take could impact the dose of CBD that can safely be used. Taking CBD with other medications may increase or decrease the effects of the other medications. This may lead to an increased chance of adverse effects from, or decreased effectiveness of, the other medications. Drug interactions were also seen in other studies of CBD in published literature. We are concerned about the potential safety of taking other medicines with CBD when not being monitored by a healthcare provider. In addition, there is limited research on the interactions between CBD products and herbs or

botanicals in dietary supplements. Consumers should use caution when combining CBD products with herbs or dietary supplements.

**Male Reproductive Toxicity:** Studies in laboratory animals showed male reproductive toxicity, including in the male offspring of CBD-treated pregnant females. The changes seen include decrease in testicular size, inhibition of sperm growth and development, and decreased circulating testosterone, among others. Because these findings were only seen in animals, it is not yet clear what these findings mean for human patients and the impact it could have on men (or the male children of pregnant women) who take CBD. For instance, these findings raise the concern that CBD could negatively affect a man's fertility. Further testing and evaluation are needed to better understand this potential risk.

In addition, CBD can be the cause of side effects that you might notice. These side effects should improve when CBD is stopped or when the amount ingested is reduced. This could include changes in alertness, most commonly experienced as somnolence (sleepiness), but this could also include insomnia; gastrointestinal distress, most commonly experienced as diarrhea and/or decreased appetite, but could also include abdominal pain or upset stomach; and changes in mood, most commonly experienced as irritability and agitation.

The FDA is actively working to learn more about the safety of CBD and CBD products, including the risks identified above and other topics, such as:

**Cumulative Exposure:** The cumulative exposure to CBD if people access it across a broad range of consumer products. For example, what happens if you eat food with CBD in it, use CBD-infused skin cream and take other CBD-based products on the same day? How much CBD is absorbed from your skin cream? What if you use these products daily for a week or a month?

**Special Populations:** The effects of CBD on other special populations (e.g., the elderly, children, adolescents, pregnant and lactating women).

**CBD and Animals:** The safety of CBD use in pets and other animals, including considerations of species, breed, or class and the safety of the resulting human food products (e.g., meat milk, or eggs) from food-producing species.

### **Some CBD Products are Being Marketed with Unproven Medical Claims and Could be Produced with Unsafe Manufacturing Practices**

Unlike the FDA-approved CBD drug product, unapproved CBD products, which could include unapproved drugs, cosmetics, foods, and products marketed as dietary supplements, have not been subject to FDA evaluation regarding whether they are effective to treat a particular disease or have other effects that may be claimed. In addition, they have not been evaluated by the FDA to determine what the proper dosage is, how they could interact with other drugs or foods, or whether they have dangerous side effects or other safety concerns.

Misleading, unproven, or false claims associated with CBD products may lead consumers to put off getting important medical care, such as proper diagnosis, treatment, and supportive care. For that reason, it's important to talk to your doctor about the best way to treat diseases or conditions with available FDA-approved treatment options.

In addition to safety risks and unproven claims, the quality of many CBD products may also be in question. The FDA is also concerned that a lack of appropriate processing controls and practices can put consumers at additional risks. For example, the agency has tested the chemical content of cannabinoid compounds in some of the products, and many were found to not contain the levels of CBD they claimed. We are also investigating reports of CBD potentially containing unsafe levels of contaminants (e.g., pesticides, heavy metals, THC).

CBD products are also being marketed for pets and other animals. The FDA has not approved CBD for any use in animals and the concerns regarding CBD products with unproven medical claims and of unknown quality equally apply to CBD products marketed for animals. The FDA recommends pet owners talk with their veterinarians about appropriate treatment options for their pets.

The FDA's top priority is to protect the public health. This priority includes making sure consumers know about products that put their health and safety at greatest risk, such as those claiming to prevent, diagnose, treat, mitigate, or cure serious diseases. For example, the agency has warned companies to stop selling CBD products they claim are intended to prevent, diagnose, treat, mitigate, or cure serious diseases such as cancer, Alzheimer's disease, psychiatric disorders and diabetes. While we have focused on these types of products, we will continue to monitor the marketplace for any product that poses a risk to public health, including those with dangerous contaminants, those marketed to vulnerable populations, and products that otherwise put the public health at risk.

### **The FDA is Continuing to Evaluate the Regulatory Frameworks for Products Containing Cannabis and Cannabis-Derived Compounds**

The FDA continues to believe the drug approval process represents the best way to ensure that safe and effective new medicines, including any drugs derived from cannabis, are available to patients in need of appropriate medical therapy. The agency is committed to supporting the development of new drugs, including cannabis and cannabis-derived drugs, through the investigational new drug and drug approval process.

We are aware that there may be some products on the market that add CBD to a food or label CBD as a dietary supplement. Under federal law, it is illegal to market CBD this way.

The FDA is evaluating the regulatory frameworks that apply to certain cannabis-derived products that are intended for non-drug uses, including whether and/or how the FDA might consider updating its regulations, as well as whether potential legislation might be appropriate. The information we have underscores the need for further study and high quality, scientific information about the safety and potential uses of CBD.

The FDA is committed to setting sound, science-based policy. The FDA is raising these safety, marketing, and labeling concerns because we want you to know what we know. We encourage consumers to think carefully before exposing themselves, their family, or their pets, to any product, especially products like CBD, which may have potential risks, be of unknown quality, and have unproven benefits.

Our Consumer Update includes a practical summary of what we know to date. As we learn more, our goal is to update you with the information you need to make informed choices about CBD products. Also, as the regulatory pathways are clarified we will take care to inform all stakeholders as quickly as possible.