



## *Promoting Illicit Drug Prevention Initiatives Nationally*

---

Therapeutic Goods Administration  
Department of Health  
PO Box 100  
Woden ACT 2606  
[www.tga.gov.au](http://www.tga.gov.au)  
[medicines.scheduling@health.gov.au](mailto:medicines.scheduling@health.gov.au)

Drug free Australia has grave concerns that the Australian Federal Government drugs' regulator is weighing up whether or not to allow cannabidiol-only (CBD) products to be sold over the counter in pharmacies.

We understand that the Therapeutic Drug Administration (TGA) is reviewing the evidence on whether to create a new Schedule 3, or 'pharmacists only' medicine, category for CBD products.

We draw your attention to the FDA having recently updated the public web link on concerns about **potential harm from CBD products, including potential liver injury, interactions with other drugs and male reproductive toxicity, as well as side effects such as drowsiness.** :

<https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis>

In **addition to these harms, there is still much we do not know about other potential risks.** There are many unanswered questions. To quote just a few from the FDA:

- *What happens if you take CBD daily for sustained periods of time?*
- *What level of intake triggers the known risks associated with CBD?*
- *How do different methods of consumption affect intake (e.g., oral consumption, topical, smoking or vaping)?*
- *What is the effect of CBD on the developing brain (such as on children who take CBD)?*
- *What are the effects of CBD on the developing fetus or breastfed newborn?*
- *How does CBD interact with herbs and other plant materials?*
- *Does CBD cause male reproductive toxicity in humans, as has been reported in studies of animals?*

**The complexity of substances, in this category, make the decision to change the Schedule too early even more high risk. According to the FDA:**

*Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is the component that produces the “high” associated with marijuana use. Much interest has been seen around CBD its potential related to health benefits.*

*Marijuana is different from CBD. CBD is a single compound in the cannabis plant, and marijuana is a type of cannabis plant or plant material that contains many naturally occurring compounds, including CBD and THC.*

*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.***

The FDA will also continue to [update our online resources](#) for consumers, researchers and industry, as well as sustain multiple lines of communication with Congress, industry, **researchers** and our regulatory partners at the federal, state, local, territorial, tribal and **international levels**.

Given the importance of answering these questions, we’re exploring a number of ways to address the data gaps as quickly as possible. This includes encouraging, facilitating and initiating more research on CBD, providing venues for industry and researchers to share new data with the agency and identifying opportunities to further collaborate with our federal partners at Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration and National Institute on Drug Abuse on this important issue.

The Therapeutic Goods Administration would be aware that all State Chief Medical Officers and the Prime Minister during this Coronavirus (COVID-19) has clearly stated that the health and welfare of the Australian Community comes first.

We are contend that not enough quality research is available regarding the benefits of CBD and the comparable harms it can cause the community. **Therefore, in the interests of the health and wellbeing of our Australian community, we recommend that now is not the time to create a new Schedule 3 for CBD products.**

**Kind Regards**

Herschel Baker  
Queensland Director Drug Free Australia  
International Liaison Director

President  
Drug Free Australia  
11 May 2020