

FDA vs Non-FDA

Why choose an FDA-approved cannabinoid-based product?

The FDA requires multiple types of studies prior to approval and continues oversight even after approval to maintain vigilance regarding patient safety. Non-FDA-approved cannabinoid-based products have not been evaluated to determine if their health benefits outweigh risks.



1. WHAT IS THE FDA?

A governing body for protecting public health

- The FDA is responsible for regulating drugs, biologics, and medical devices, as well as food content¹
- Its mandate is to ensure safe and effective drugs are available to improve the health of people in the US²
- One of several regulatory bodies in the US intended to protect consumers³

2. FDA STANDARDS AND REGULATIONS

The FDA's standards and regulations are designed to protect the consumer

- The FDA requires randomized controlled clinical trials, the highest level of scientific evidence⁴
- All FDA-approved medications must meet agency standards for safety and efficacy⁵

3. CANNABIS REGULATION

The patchwork of regulation and enforcement is concerning

- State and federal laws are inconsistent and conflicting, creating gaps in consumer protection⁶
- No standardized testing or independent oversight for non-FDA-approved products⁷

4. UNDERREGULATED PRODUCTS

Researchers consistently find inconsistencies in purity, quality, and labeling

- Although many states have legalized cannabis, testing requirements are frequently lacking and are not standardized⁷
- Many products contain inaccurate levels of cannabinoids, and some contain toxins and heavy metals⁸⁻¹³

5. TAKE ACTION

Prioritize consumer safety and health

- Support evidence-based research within the FDA pathway
- Seek FDA-approved medications
- Strengthen policy for the future of cannabinoid science and medicine

FDA: Food and Drug Administration; US: United States.

1. <https://www.fda.gov/about-fda/what-we-do> 2. <https://www.fda.gov/about-fda/fda-organization/center-drug-evaluation-and-research-cder> 3. <https://www.fda.gov/about-fda/what-we-do/what-does-fda-regulate> 4. Van Norman GA. *JACC Basic Transl Sci.* 2016 Aug 29;1(5):399-412. 5. <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved> 6. Sarma ND et al. *J Nat Prod.* 2020;83(4):1334-1351. 7. <https://www.ncsl.org/health/statemedical-cannabis-laws> 8. Spindle TR et al. *JAMA Netw Open.* 2022;5(7):e2223019. 9. Johnson E et al. *Drug Alcohol Depend.* 2022;237:109522. 10. Gidal BE et al. *Front Pharmacol.* 2024;15:1335441. 11. Dubrow GA et al. *J Food Compos Anal.* 2021;97:103800. 12. Gardener H et al. *Sci Total Environ.* 2022;851(Pt 1):158110. 13. Jameson LE et al. *Environ Health Perspect.* 2022;130(9):97001.