

UNDERSTANDING

CANNABINOID PRODUCTS

Food & Drug Administration (FDA)- Approved Cannabinoid Products^{1,2}

Plant-Based and Synthetic Medicines

Non-FDA-Approved Cannabinoid Products³

Hemp-Derived Products and Medical Marijuana

STUDY EVIDENCE & REQUIREMENTS

Studied in placebo-controlled clinical trials in patients to determine safety, effectiveness and recommended dosing. Public disclosure of clinical trials required.



Randomized clinical studies have not been conducted. Public disclosure of smaller, informal studies not required.

MANUFACTURING

Produced according to regulated good manufacturing practices (GMP) in an FDA-inspected facility. FDA-approved medications must adhere to strict specifications that ensure batch-to-batch consistency and stable shelf life.



Testing standards vary from state to state, and some states require no testing. There are no federal standards; FDA does not inspect the manufacturing sites for adherence to GMP.

QUALITY STANDARDS

Meet FDA standards for stability and consistency as well as ensure that the manufacturer meets its own product quality specifications. Tested to confirm consistent concentrations of cannabinoids and other ingredients listed on the label. Inactive ingredients must be identified and documented.



Non-prescription, non-FDA-approved cannabinoid products are not consistently regulated at the state level. There are no federal testing standards to ensure accuracy or consistency; other ingredients are unknown and not regulated.⁴

LEGALITY

Legal in every state like all other FDA-approved prescription drugs. Unlike other cannabis-based products, once FDA approved, they are removed from Schedule I.



Restrictions to access vary by state.⁵ Healthcare providers can "recommend" but not prescribe hemp products or marijuana, as they are illegal at the federal level. Interstate transportation of these products is federally illegal.

COVERAGE

Eligible for insurance coverage.



Insurance coverage is rare.

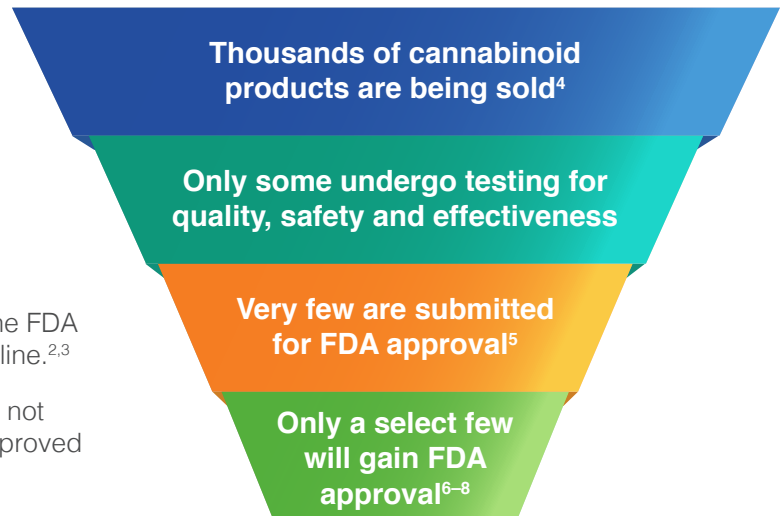
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DID YOU KNOW?

Only certain cannabinoid products have undergone or are undergoing a federal testing and approval process.

- The rigorous FDA approval process is undertaken in an effort to establish the efficacy, safety and quality of a medicine before use by the general public.¹
- FDA-approved medicines are available by prescription in both specialty and/or retail pharmacies, not dispensaries.
- Cannabinoid products that have not undergone the FDA approval process are sold in dispensaries and online.^{2,3}
- Non-FDA-approved cannabinoid products should not be considered substitutes or generics for FDA-approved medicines, as outlined on the previous page.



There are approved prescription cannabinoid medicines available now.

The FDA has approved one medication consisting of highly-purified, plant-derived cannabidiol (CBD), a cannabinoid lacking the high associated with marijuana,⁹ and three medications made from synthetic cannabinoids, most similar to tetrahydrocannabinol (THC).¹⁰⁻¹²

Additionally, a medication that combines two types of cannabinoids, THC and cannabidiol (CBD), has been studied and approved for use outside the U.S.¹³

For more information, visit CannabinoidClinical.com.

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