FDA-Approved versus Non–FDA Approved Cannabinoid Products

Food & Drug Administration (FDA)-Approved Cannabinoid Products[1,2]	Non–FDA Approved Cannabinoid Products[3]
Plant-Based and Synthetic Medicines	Hemp-Derived Dispensary Products and Medical Marijuana
Study Evidence & Requirements	
✓ Studied in placebo-controlled, publicly disclosed clinical trials with large patient samples to determine efficacy, safety, and recommended dosing.	Randomized clinical studies have not been conducted. Public disclosure of smaller, informal studies not required.
Manufacturing	
✓ Produced according to regulated current good manufacturing practices (cGMP). FDA-approved medications must adhere to strict specifications that ensure 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 cGMP.
Quality Standards	
✓ Meets FDA standards for quality, stability, consistency. Tested to ensure they contain the consistent concentrations of cannabinoids and other product ingredients listed on the label.	Non-prescription, non–FDA approved cannabinoid products are subject to inconsistent regulation at the state level. There are no federal standards for testing to ensure accuracy and consistency.[4]
Legality	
✓ Federally legal as prescribed; similar to other DEA-controlled prescription medicines.	Restrictions to access vary by state.[5] Healthcare providers can “recommend” but not prescribe hemp-derived dispensary 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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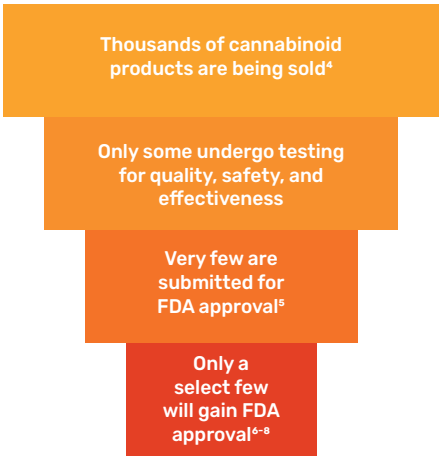
Did You Know?

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 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.

In fact, the FDA has approved 3 synthetic cannabinoids and 1 plant-derived cannabinoid. They are indicated to treat:

Tetrahydrocannabinol (THC) and THC analogs (synthetic):

- Anorexia associated with weight loss in adult patients with AIDS[9,10]
- Nausea and vomiting associated with chemotherapy in adult patients who failed conventional antiemetics[9–11]

Cannabidiol (plant derived):

- Seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients 2 years of age and older

Additionally, a medication that combines 2 types of cannabinoids, THC and cannabidiol (CBD), has been studied and approved for use outside the US.[12]

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