

FDA and DEA Cannabis Overview

<p>https://www.fda.gov/about-fda/what-we-do</p> <p>https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process</p>	<ol style="list-style-type: none"> 1. What does the Food and Drug Administration (FDA) do? 2. How does this relate to cannabis? 	<ol style="list-style-type: none"> 1. “It ensures the safety of all food except for meat, poultry and some egg products; ensures the safety and effectiveness of all drugs, biological products (including blood, vaccines and tissues for transplantation), medical devices, and animal drugs and feed; and makes sure that cosmetics and medical and consumer products that emit radiation do no harm.” 2. Hemp-derived cannabis products (e.g., CBD) are legal under the Agricultural Improvement Act of 2018 (AKA Farm Bill). The FDA has not approved a marketing application for cannabis for the treatment of any specific disease or condition. The FDA has approved one cannabis-derived drug product: Epidiolex (cannabidiol), and three synthetic cannabis-related drug products: Marinol (dronabinol), Syndros (dronabinol), and Cesamet (nabilone). These approved drug products are only available with a prescription from a licensed healthcare provider. Importantly, the FDA has not approved any other cannabis, cannabis-derived, or cannabidiol (CBD) products currently available on the market.
<p>https://www.fda.gov/media/128156/download</p> <p>https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd</p>	<p>Where can I learn more about FDA regulations on cannabis?</p>	<ul style="list-style-type: none"> • FDA – slide show on their website breaking down FDA regs with cannabis FDA regulations page including media and news relating • Consumer Information • FDA Communications • Regulatory Resources • Questions and Answers

<ul style="list-style-type: none"> • https://sencanada.ca/content/sen/committee/371/ille/library/history-e.htm#E.%20The%201936%20Geneva%20Trafficking%20Convention • https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3839489/ • https://www.natlawreview.com/article/2018-farm-bill-legalizes-hemp-obstacles-to-sale-cbd-products-remain 	<p>What are the related laws in US history for cannabis?</p>	<ul style="list-style-type: none"> • 1936 Geneva Trafficking Convention E. The 1936 Geneva Trafficking Convention Based on initiatives of the International Police Commission – forerunner of the International Criminal Police Organization (INTERPOL) – negotiations had begun in 1930 to develop a treaty to stem the illicit drug traffic and harshly punish traffickers through criminal sanctions. In 1936, the Convention for the Suppression of the Illicit Traffic in Dangerous Drugs (1936 Trafficking Convention) was concluded in Geneva. The U.S., led by Anslinger, had attempted to include in the treaty the criminalization of all activities – cultivation, production, manufacture and distribution – related to the use of opium, coca (and its derivatives) and cannabis for non-medical and non-scientific purposes. Many countries opposed this and the focus remained on illicit trafficking. Article 2 of the Convention called upon signatory countries to use their national criminal law systems to "severely" punish, "particularly by imprisonment or other penalties of deprivation of liberty," acts directly related to drug trafficking. The U.S. refused to sign the final version. Despite its minimal overall effect, the 1936 Trafficking Convention represented a turning point: all the previous treaties had dealt primarily with the regulation of "legitimate" drug activities, whereas the 1936 Trafficking Convention now made such activities an international crime subject to penal sanctions. • 1970 the Controlled Substances Act https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3839489/ The Controlled Substances Act is the federal statute that regulates the manufacture and distribution of controlled substances such as hallucinogens, narcotics, depressants, and stimulants. The Act categorizes drugs into five classifications or “schedules” based on their potential for abuse, status in international treaties, and any medical benefits they may
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		<p>provide. Generally speaking, drugs included in Schedule 1 are the most strictly regulated, because they are deemed to have no medical value.</p> <ul style="list-style-type: none"> • <u>Agricultural Act of 2014. Section 7606</u> Congress previously enacted Section 7606 of the Agriculture Act of 2014 (the “2014 Farm Bill”), which initially – albeit less robustly – legalized the domestic production of hemp within the United States. The 2014 Farm Bill established a framework for hemp pilot programs that permitted states to engage in the cultivation and research of hemp under certain circumstances. The 2014 Farm Bill defined hemp as Cannabis, “whether growing or not, with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3% on a dry weight basis.” • 2018 Farm Bill: <ul style="list-style-type: none"> -The 2018 farm bill went several steps further and legalized the production of hemp as an agricultural commodity while removing it from the list of controlled substances. -The bill outlined actions that would be considered violations of the law, such as producing a plant with higher than 0.3 percent THC content or cultivating hemp without a license; <p>Section 10113 of the 2018 Farm Bill defines hemp more broadly than the 2014 Farm Bill defined "industrial hemp" thus eliminating any question that both the plants and products derived from the plants are legal, so long as the THC concentration does not exceed 0.3 percent. In that regard, section 10113 provides that "the term 'hemp' means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." Any cannabis plant or product that contains more than 0.3 percent THC will still be considered marijuana under federal law.</p>
https://www.congress.gov/bill/116th-congress/house-bill/3884	Is cannabis legal federally?	<ul style="list-style-type: none"> • Certain aspects such as hemp with 2018 Farm Act. • On the dockets Marijuana Opportunity Reinvestment and Expungement Act of 2019 or the MORE Act of 2019 <p>This bill decriminalizes marijuana.</p>

		<p>Specifically, it removes marijuana from the list of scheduled substances under the Controlled Substances Act and eliminates criminal penalties for an individual who manufactures, distributes, or possesses marijuana.</p> <p>While this Act has not yet passed, revised versions introduced in 2020 and 2021 are still actively being debated in Congress.</p>
https://www.dea.gov/about/mission	What does the Drug Enforcement Agency (DEA) do?	<p>The mission of the Drug Enforcement Administration (DEA) is to enforce the controlled substances laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.</p>
https://www.dea.gov/operations/eradication-program	What are certain programs the DEA have involving cannabis or marijuana?	<ul style="list-style-type: none"> • Marijuana is the only major drug of abuse grown within the U.S. borders. The DEA is aggressively striving to halt the spread of cannabis cultivation in the United States. To accomplish this, the DEA initiated the Domestic Cannabis Eradication/Suppression Program (DCE/SP), which is the only nationwide law enforcement program that exclusively targets Drug Trafficking Organizations (DTO) involved in cannabis cultivation. • RESEARCH On May 14, 2021, the Drug Enforcement Administration took an important step to increase opportunities for medical and scientific research. DEA is nearing the end of its review of certain marijuana grower applications, thereby allowing it to soon register additional entities authorized to produce marijuana for research purposes. Currently, the National Center for the Development of Natural Products at the University of Mississippi is the only approved supplier of marijuana for research purposes in the United States, and that production has been exclusively for the National Institute on Drug Abuse.