FDA Drug Topics: Cannabis and Cannabis-Derived Products – For Healthcare Practitioners

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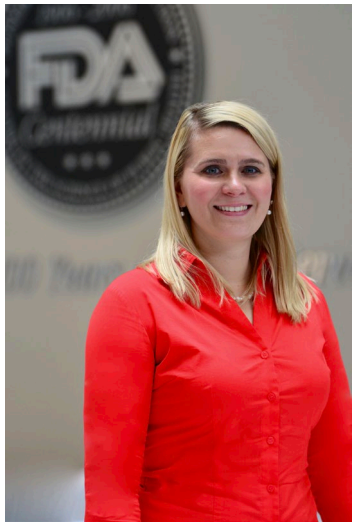

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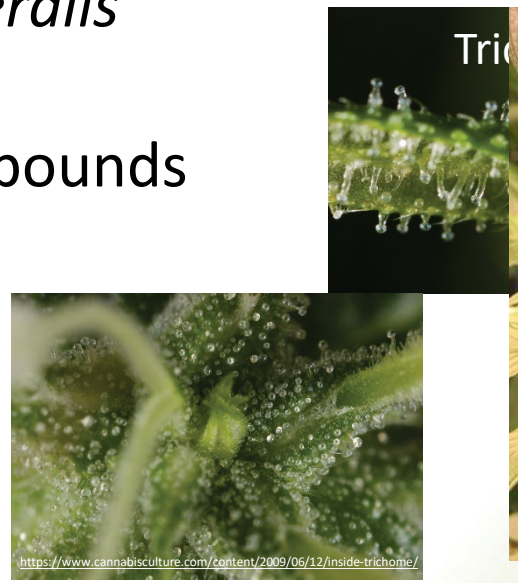
What is Cannabis?

- Cannabis is a genus of flowering plant that includes three species: *Cannabis sativa, indica* and *ruderalis*

- Plant contains hundreds of compounds
  - More than 100 cannabinoids
  - More than 100 terpenes
  - Other phytochemicals present

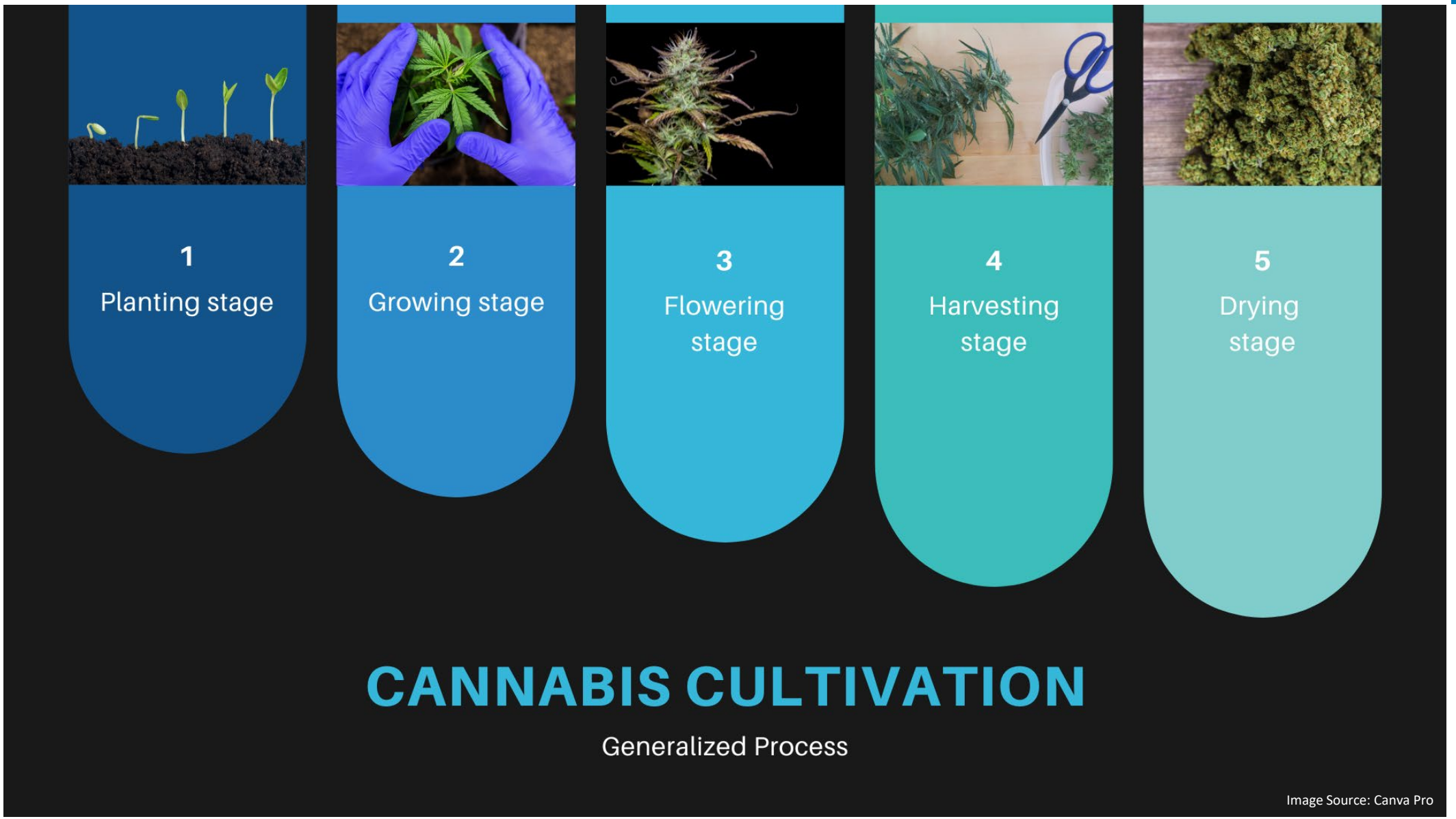
- Commonly known compounds
  - Cannabidiol (CBD)
  - Tetrahydrocannabinol (THC)

- Unknown number of cultivars
  - Human cultivation for specific traits
  - To create new varieties



Source: POLITICO, C. Rivero published 10/21/2019

What is Cannabis?



What is Cannabis?

Term: “Marihuana” or “Marijuana”

- Parts of the *Cannabis sativa* plant have been controlled under the Controlled Substances Act (CSA) since 1970
- Under the drug class "Marihuana" (commonly referred to as "marijuana") [21 U.S.C. 802(16)]
- "Marihuana" is currently listed in Schedule I of the CSA due to its high potential for abuse, which is attributable in large part to the psychoactive effects of THC, and the absence of a currently accepted medical use of the plant in the U.S.

> 0.3% delta-9 THC > by dry weight

Term: “Hemp”

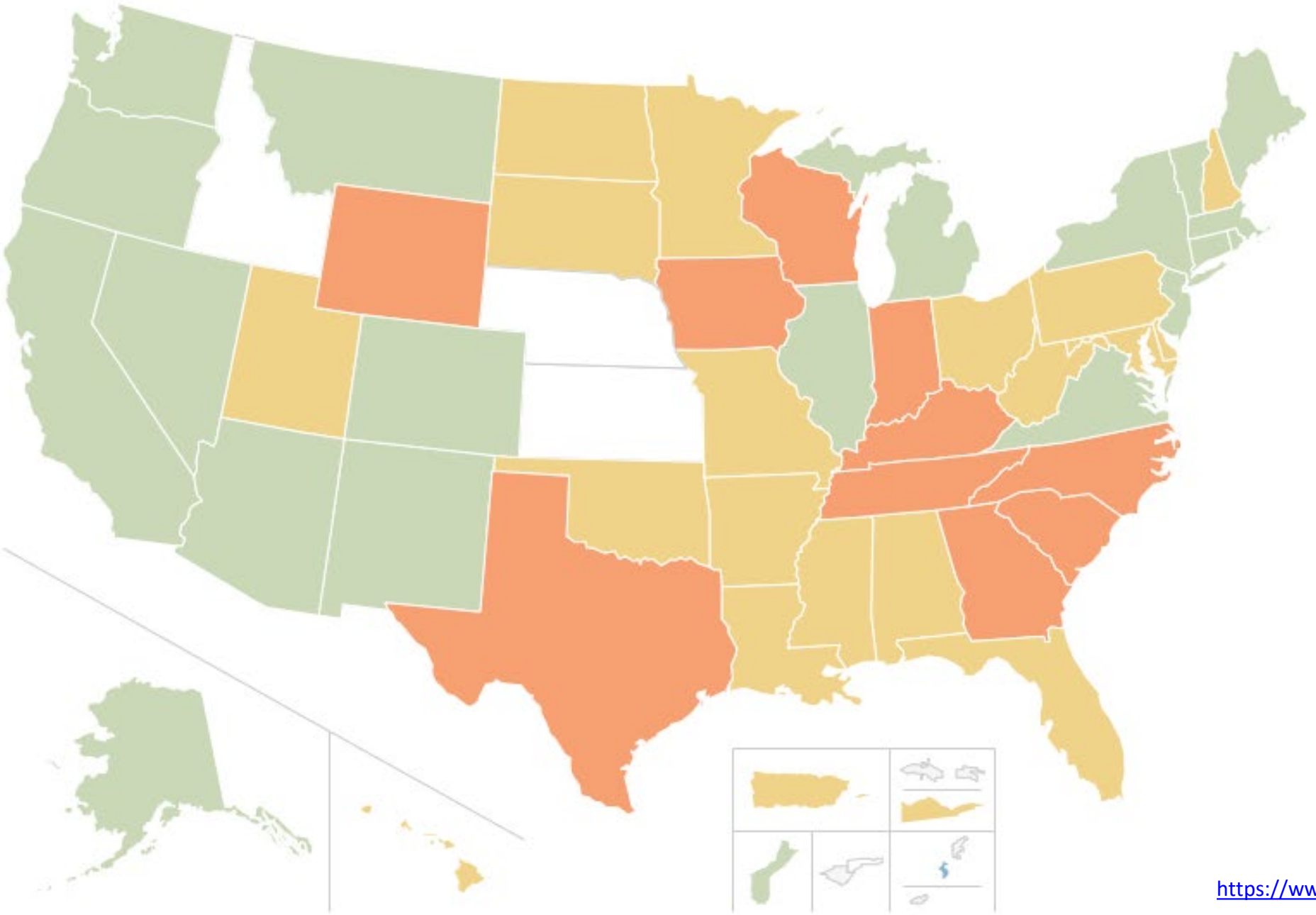
- Agriculture Improvement Act of 2018, Pub. L. 115-334, (the 2018 Farm Bill) was signed into law on Dec. 20, 2018
- Removed hemp from regulation by the Drug Enforcement Administration (DEA) under Schedule I of the CSA
- The Farm Bill defined hemp as *Cannabis sativa* L. with a delta-9 THC concentration of not more than 0.3 percent (on a dry weight basis)
- Cannabis plants and derivatives that contain **no more than 0.3 percent delta-9 THC on a dry weight basis** are no longer controlled substances under federal law

Image Source: Canva Pro

Cannabis Use at State-level

- Per the National Conference of State Legislators (NCSL)
  - "Medical-Use"
    - As of Feb. 3, 2023: 37 states, 3 territories and the District of Columbia allow medical use of cannabis products by qualified individuals
  - "Non-Medical/Adult-Use":
    - As of Nov. 9, 2022: 21 states, 2 territories and the District of Columbia have enacted measures to regulate cannabis for adult non-medical use
  - "Low THC, high cannabidiol (CBD)":
    - As of May 2022: 10 states allow use of these products for medical reasons in limited situations or as a legal defense

State Regulated Cannabis Programs, May 2022



https://www.ncsl.org/health/state-medical-cannabis-laws

State Medical Cannabis Program Laws: Examples

- Examples below are provided as excerpts from NCSL “Table 1. State Medical Marijuana/Cannabis Program Laws”
- See full text at https://www.ncsl.org/health/state-medical-cannabis-laws - for information purposes only

State	Statutory Language (year)	Patient Registry or ID cards	Allows Dispensaries	Specifies Conditions	Recognizes Patients from Other States	State Allows for Retail Sales/ Non Medical Adult Use
California	Proposition 215 (1996) SB 420 (2003)	Yes	Yes (cooperatives and collectives)	No	No	Yes. Proposition 64 (2016)
Colorado Medical program info -Non medical use info	Amendment 20 (2000)	Yes	Yes	Yes	No	Yes. Amendment 64 (2012) Task Force Implementation Recommendations (2013) Analysis of CO Amendment 64 (2013) Colorado Marijuana Sales and Tax Reports 2014 "Edibles" regulation measure FAQ about CO cannabis laws by the Denver Post.
Massachusetts	Question 3 (2012) Regulations (2013)	Yes	Yes	Yes	No	Yes. Question 4 (2016)
Maryland	HB 702 (2003) SB 308 (2011) HB 180/SB 580 (2013) HB 1101- Chapter 403 (2013) SB 923 (signed 4/14/14) HB 881- similar to SB 923	Yes	Yes	Yes	No	Yes. Question 4 (2022)

State Medical Cannabis Program Laws: Examples

- S. Pruyn, Q. Wang, C. Wu, and **C. Taylor.** Quality Standards in State Programs Permitting Cannabis for Medical Uses. *Cannabis and Cannabinoids Research*. **2022,** Dec;7(6):728-735. doi.org/10.1089/can.2021.0164

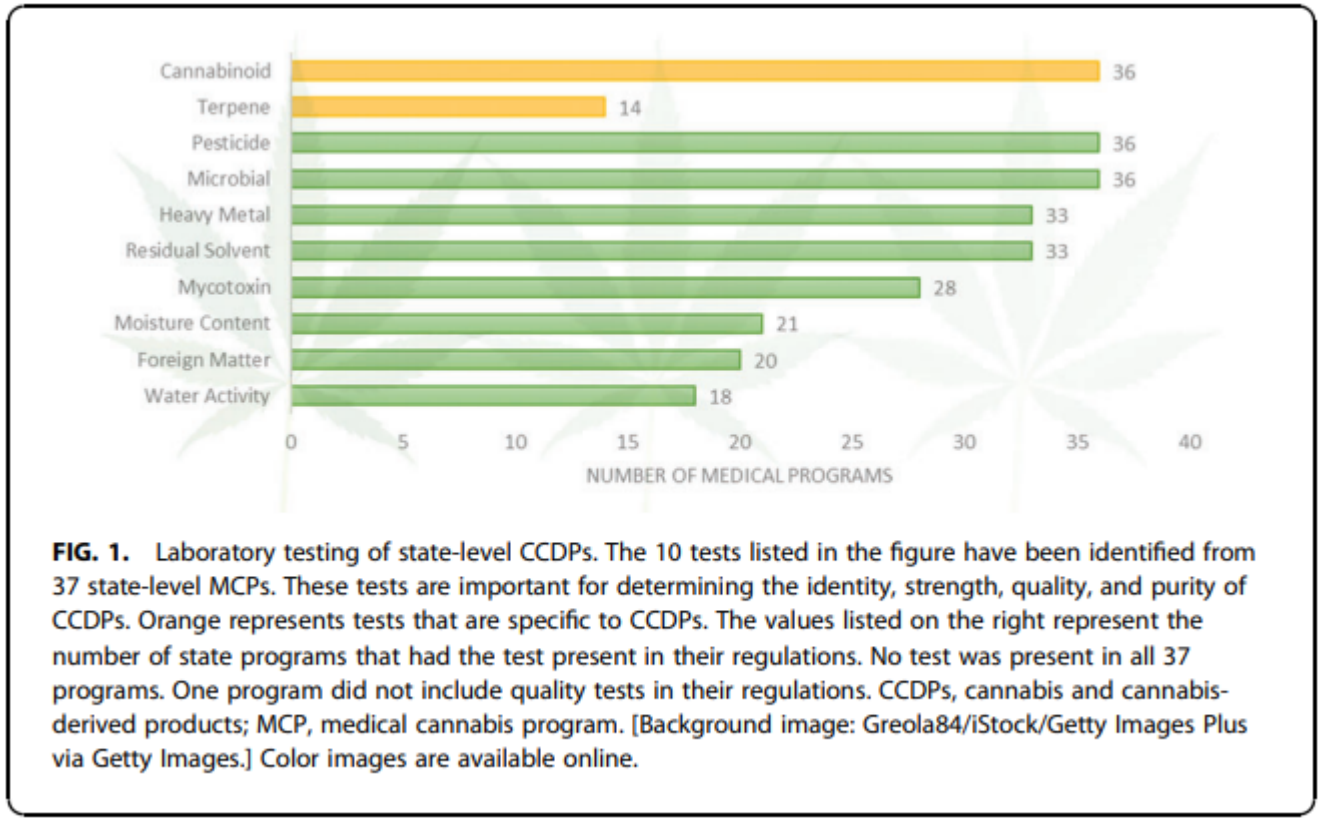
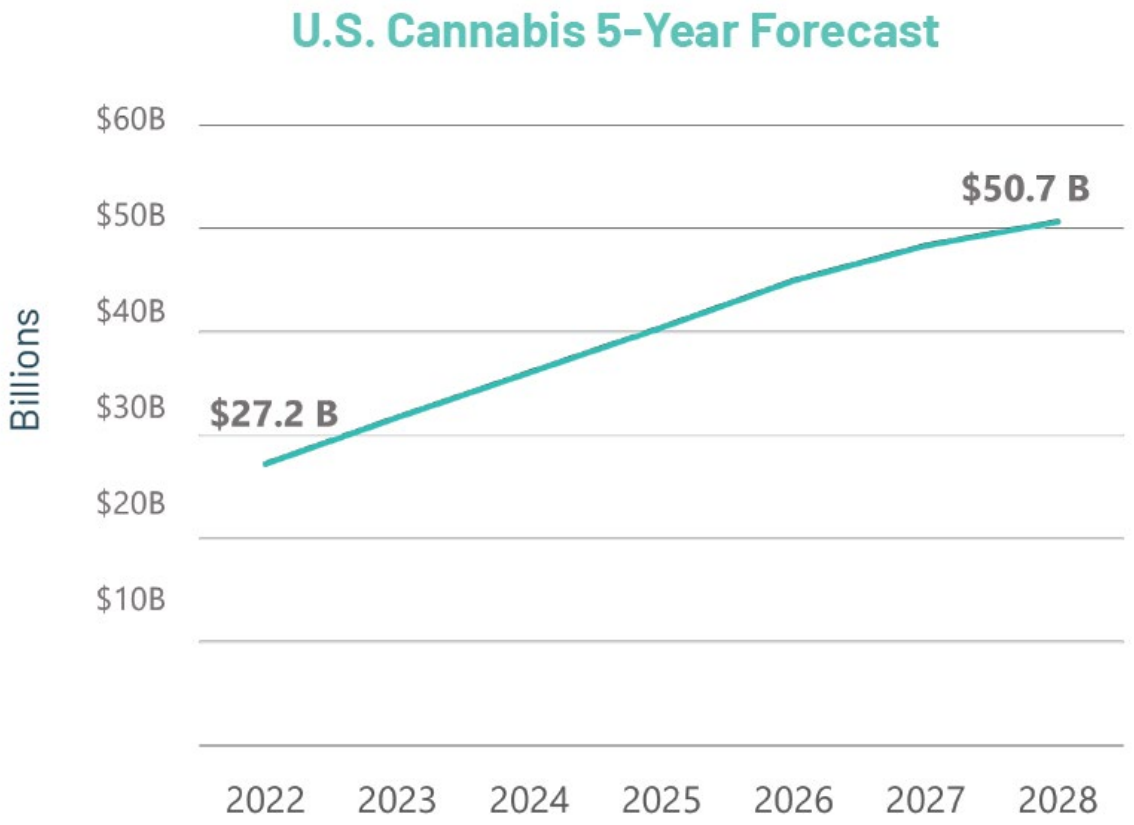
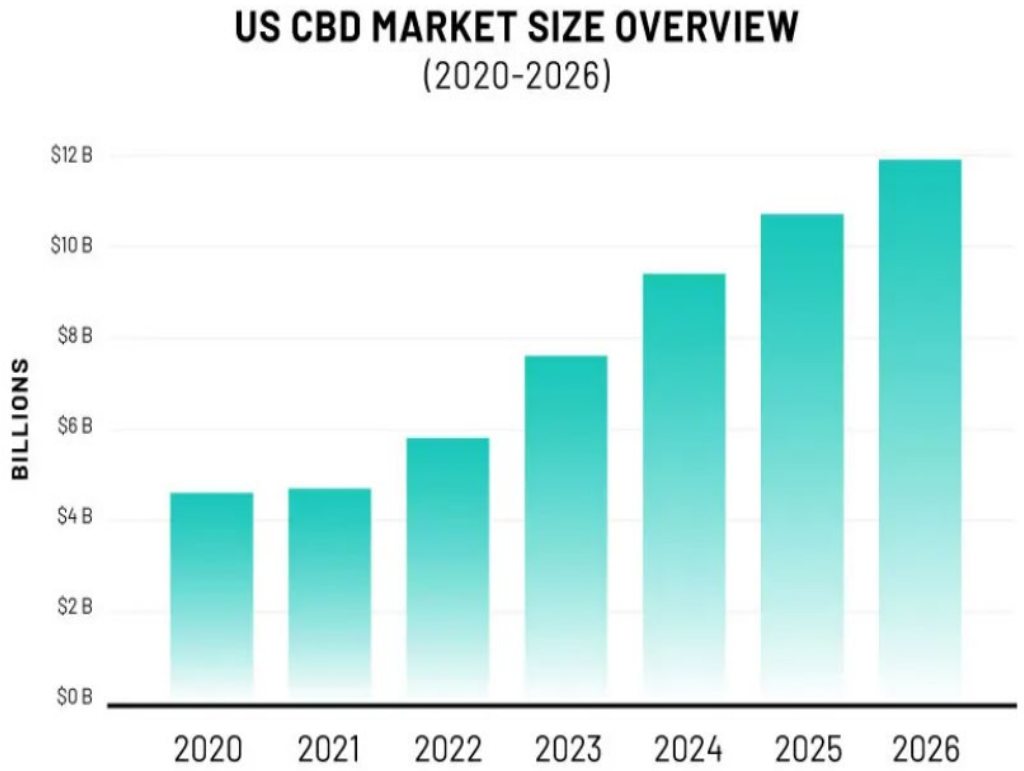


FIG. 1. Laboratory testing of state-level CCDPs. The 10 tests listed in the figure have been identified from 37 state-level MCPs. These tests are important for determining the identity, strength, quality, and purity of CCDPs. Orange represents tests that are specific to CCDPs. The values listed on the right represent the number of state programs that had the test present in their regulations. No test was present in all 37 programs. One program did not include quality tests in their regulations. CCDPs, cannabis and cannabis-derived products; MCP, medical cannabis program. [Background image: Greola84/iStock/Getty Images Plus via Getty Images.] Color images are available online.

Cannabis is $27B+ Market Predicted to Grow



Source: Brightfield Group 2023



Source: Brightfield Group 2021

Cannabis Product Types

- Tinctures
- Capsules
- Topicals
- Beauty and Personal Care
- Vape Oil and Cartridges
- Combustible/Flower
- For Pets
- Gummies
- Beverages
- Other “Edibles”
- Approved Drug

FDA Responsibilities

Regulated Products include:

Human Foods (e.g., conventional foods, dietary supplements, food additives)

Drugs (including prescription and non-prescription)

Biologics (e.g., vaccines, blood and blood products)

Medical Devices (e.g., tongue depressors, pacemakers)

Electronic Products that give off radiation (e.g., microwave oven, X-ray equipment)

Cosmetics (e.g., skin moisturizers, lipsticks, eye and facial make-up, nail polish, cleansing shampoos)

Veterinary Products (e.g., animal foods, animal drugs)

Tobacco Products (e.g., cigarettes, smokeless tobacco)

FDA Authority

Federal Food, Drug & Cosmetic Act (FD&C Act)

- Federal law enacted by Congress
- Along with other federal laws it establishes legal framework within which FDA operates

FDA regulations

- Develops regulations based on law set forth in FD&C Act or other laws under which FDA operates
- FDA regulations can be found in Title 21 of the Code of Federal Regulations (21 CFR)

FDA guidance

- Follows procedures required by its "Good Guidance Practice" regulation to issue FDA Guidance
- Describe FDA's current thinking on a regulatory issue

FDA Basics: https://www.fda.gov/aboutfda/transparency/basics/ucm194909.htm

Overview of FDA Drug Authority

- Under the FD&C Act:
  - Any product, including a cannabis product (hemp or otherwise), that is **marketed with a claim of therapeutic benefit, or with any other disease claim, is considered to be a drug**
  - A new drug must be approved by the FDA for its intended use before it may be introduced into interstate commerce

The Farm Bill's Impact on FDA Authorities

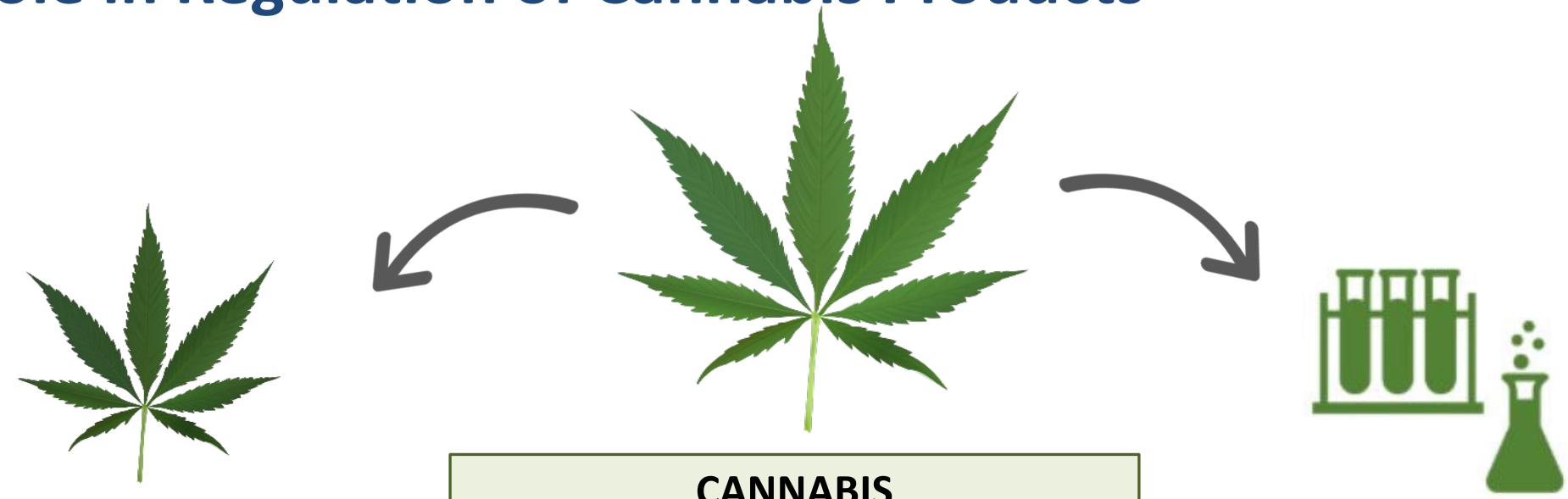
- FDA's authorities under the FD&C Act and section 351 of the Public Health Service (PHS) Act were **specifically preserved by the Farm Bill**
  - Cannabis and cannabis-derived products, including products containing CBD, are subject to the same authorities and requirements as FDA-regulated products containing any other substance

- FDA authorities include:
  - Scientific and regulatory support for research on **potential therapeutic uses** of CBD products and **approval of CBD drug products** that are safe and effective
  - **Regulation of CBD products** (e.g., as foods including dietary supplements, drugs, cosmetics)
  - **Enforcement actions as necessary** against violative CBD products, particularly those that present serious human or animal health risks

- Many products containing CBD **are illegal under the Food, Drug, and Cosmetic Act** (e.g., illegal to make therapeutic claims unless an approved drug, illegal to put in food or dietary supplements)

Agriculture Improvement Act of 2018 ("Farm Bill," Pub L. No: 115-1072)

FDA Role in Regulation of Cannabis Products



Cannabis-derived compounds

- Compounds occurring naturally in the plant – like **CBD** and **THC**
- These compounds are extracted directly from the plant
- Can be used to manufacture drug products
- Example: highly-purified CBD extracted from the plant
- Agency approved one cannabis-derived drug product: Epidiolex (cannabidiol)

CANNABIS

- *Cannabis sativa* L. is a plant that contains over 80 different naturally occurring compounds called "cannabinoids"
- Two well-known cannabinoids:
  - **Cannabidiol (CBD)**
  - **Tetrahydrocannabinol** (**THC)**
- Plants are grown to produce varying concentrations of cannabinoids – **THC** or **CBD**
- These plant variations are called cultivars

Cannabis-related compounds

- These synthetic compounds are created in a laboratory
- Can be used to manufacture drug products
- Some synthetic compounds may also occur naturally in the plant and some may not
- Examples: Synthetically-derived dronabinol (also naturally occurring) and nabilone (not naturally occurring)
- Agency approved 3 synthetic cannabis-related drug products: Marinol & Syndros (dronabinol), Cesamet (nabilone)

FDA and Cannabis: Research and Drug Approval Process

Cannabis – Derived Compounds

Cannabis-derived compounds

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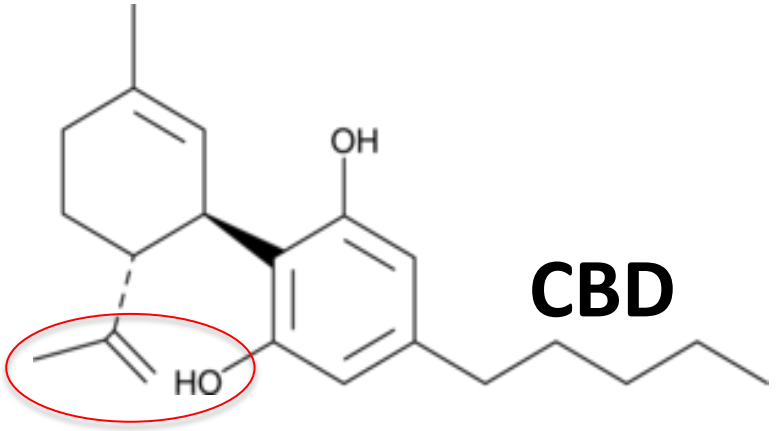
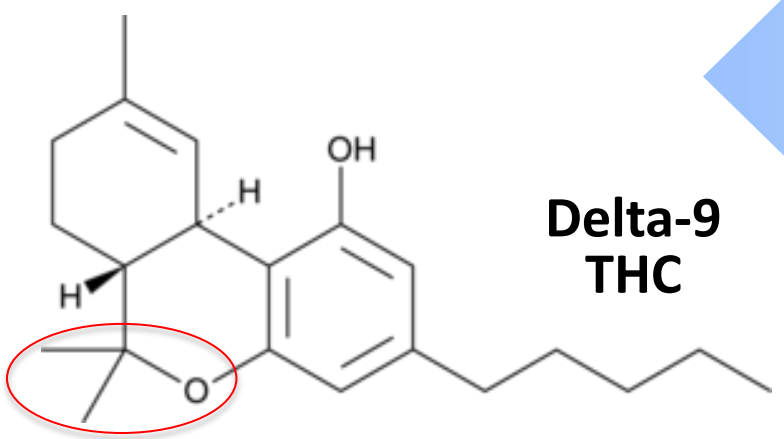


CBD



Delta-9 THC

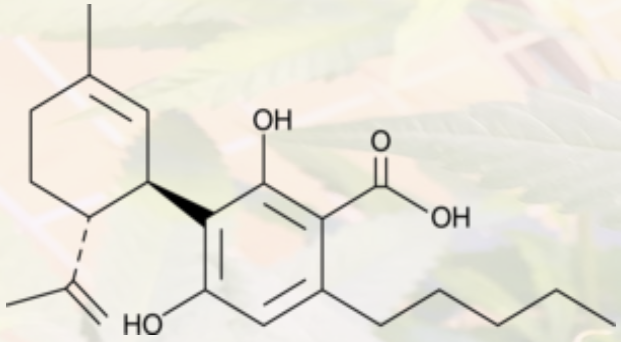
Examples of other cannabis-derived compounds

- **Other Cannabinoids**: CBDA, THCA, CBN, CBDV, CBC, CBG, CBGA, THCV, etc.
- **Terpenes**: Myrcene, Limonene, Linalool, Caryophyllene, Pinene, etc.

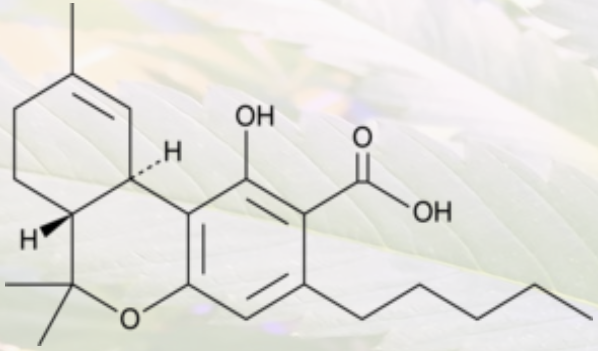
[FDA and Cannabis: Research and Drug Approval Process]

Cannabis – Derived Compounds: Cannabinoids

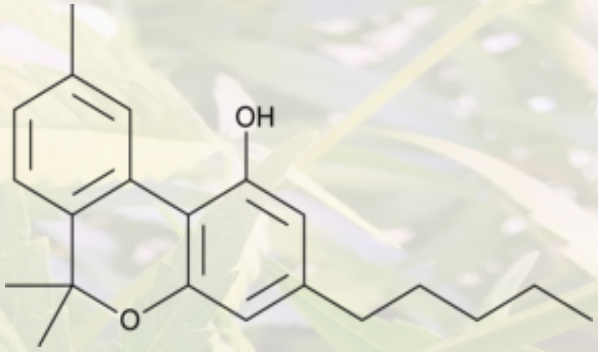
Cannabidiolic Acid (CBDA)



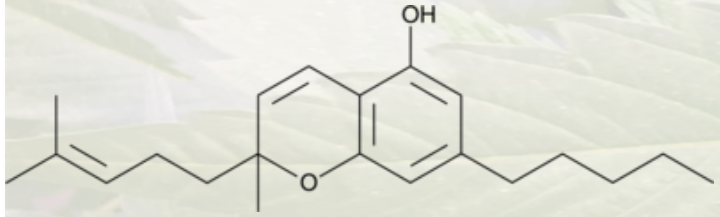
Tetrahydrocannabinolic Acid (THCA)



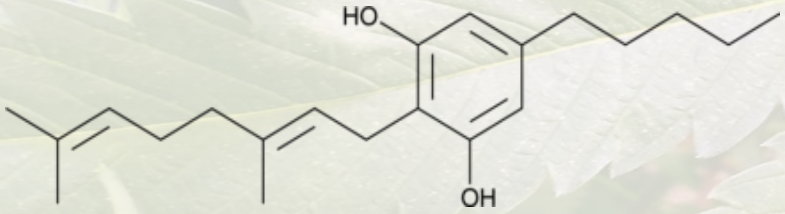
Cannabinol (CBN)



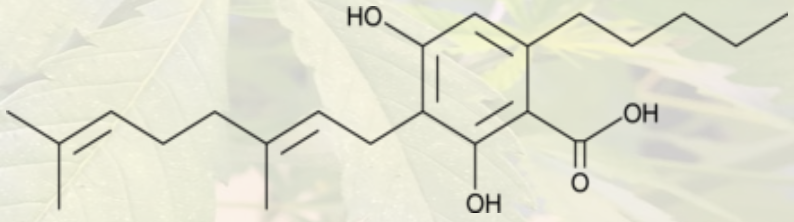
Cannabichromene (CBC)



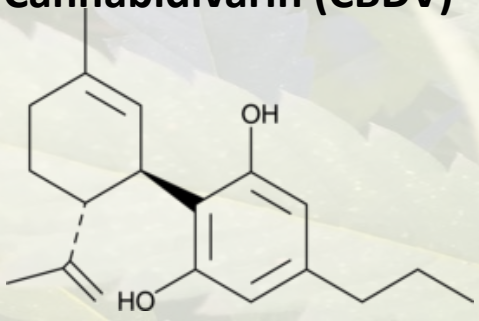
Cannabigerol (CBG)



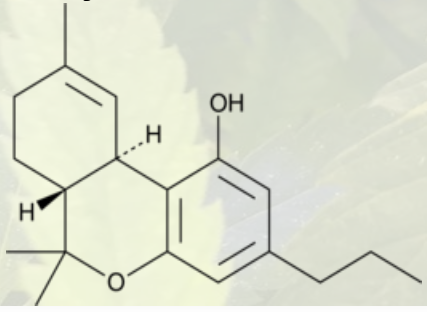
Cannabigerolic Acid (CBGA)



Cannabidivarin (CBDV)



Tetrahydrocannabivarin (THCV)



>100 different cannabinoids naturally occur in cannabis

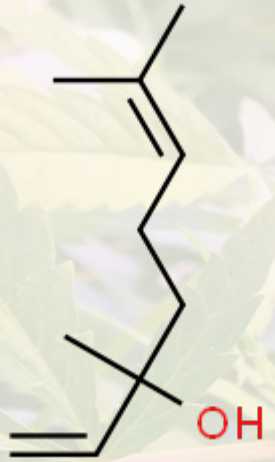
Chemical structures from: https://www.caymanchem.com/product/90080/cannabidiol; https://www.caymanchem.com/product/12068/%CE%B49-thc; https://www.caymanchem.com/product/18090/cannabidiolic-acid-(crm); https://www.caymanchem.com/product/ISO60175/thca-a-(crm); https://www.caymanchem.com/product/25495/cannabinol; https://www.caymanchem.com/product/ISO60163/(%C2%B1)-cannabichromene-(crm) ; https://www.caymanchem.com/product/15293/cannabigerol ; https://www.caymanchem.com/product/9001572/cannabigerolic-acid ; https://www.caymanchem.com/product/20165/cannabidivarin-(crm); https://www.caymanchem.com/product/18091/tetrahydrocannabivarin-(crm)

Cannabis – Derived Compounds: Terpenes

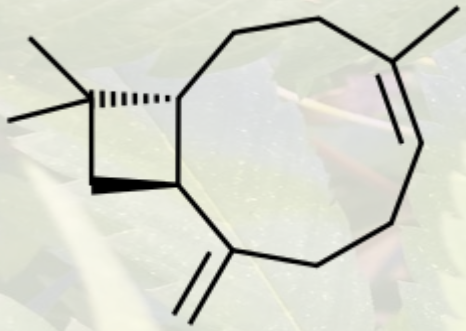
Myrcene

Limonene

Linalool



Caryophyllene



Pinene

- **At least 20,000 different terpenes exist in nature**
- **>100 different terpenes naturally occur in cannabis**

Chemical structures from: http://www.chemspider.com/Chemical-Structure.28993.html ; http://www.chemspider.com/Chemical-Structure.388386.html?rid=92f338e2-4be3-45d9-98ba-b0a485adb345 ; http://www.chemspider.com/Chemical-Structure.13849981.html?rid=e442d668-4833-47b0-bb73-6e9005eb035f&page_num=0 ; http://www.chemspider.com/Chemical-Structure.4444855.html?rid=2ed455f9-002e-498e-98c9-4b7aa557aabf&page_num=0 ; http://www.chemspider.com/Chemical-Structure.74205.html?rid=315cfc32-16fd-4ec1-af7a-8811c4c5eeba&page_num=0

Cannabis Drug Development

Four products approved by FDA; with re-scheduling drug control actions upon approval:

1. Marinol (dronabinol) (1985): nausea from cancer chemotherapy; anorexia associated with AIDS
   →**Schedule III (under the Controlled Substances Act)**

2. Cesamet (nabilone) (1985 (2006)): nausea from cancer chemotherapy → **Schedule II**

3. Syndros (dronabinol) (2016): nausea from cancer chemotherapy; anorexia associated with AIDS
   → **Schedule II**

4. Epidiolex (CBD) (2018): for childhood seizures & Tuberous Sclerosis Complex → Originally Schedule V but now **No longer controlled**

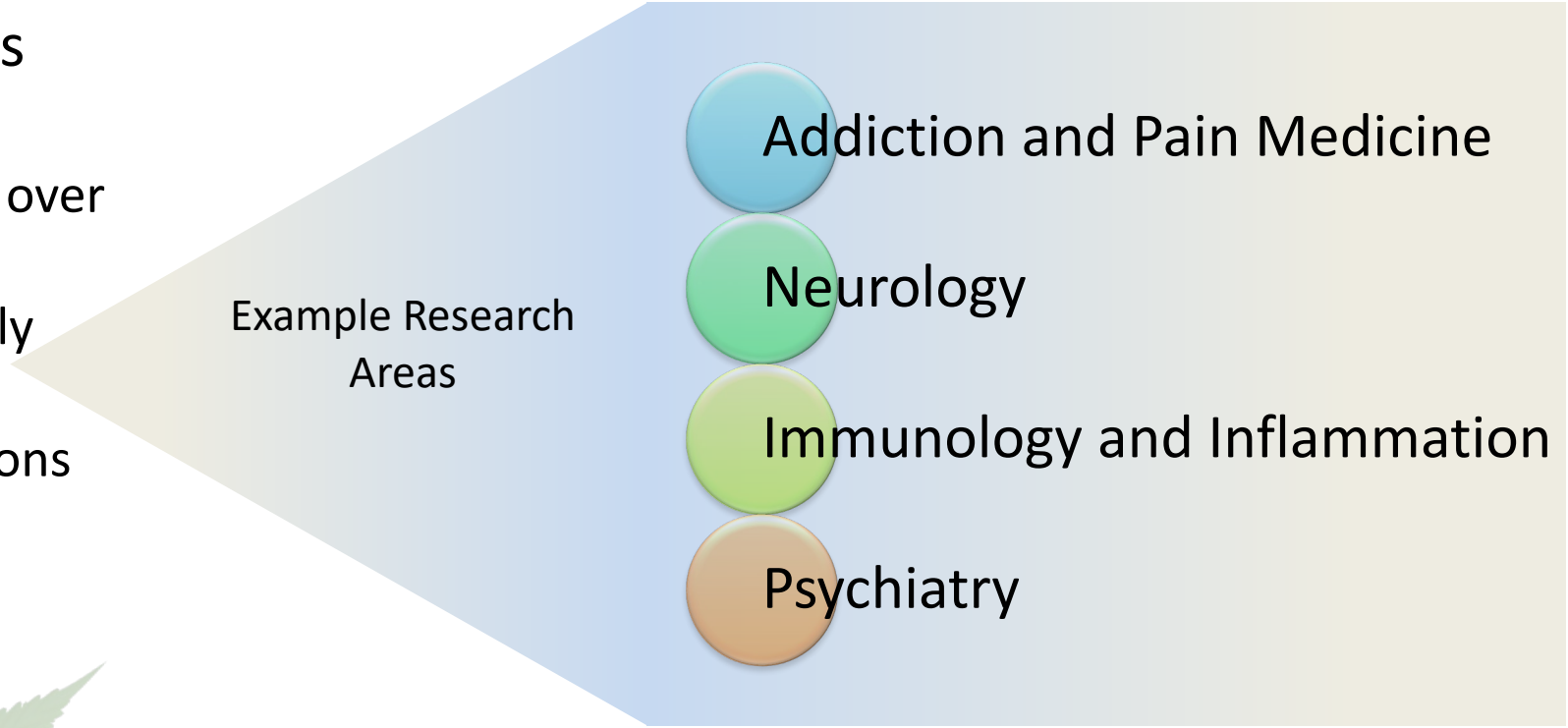
Photo: https://prescriptiongiant.com/product/cesamet-generic-nabilone/

Photo: https://www.syndros.com/what-is-syndros/how-to-use

Photo: https://www.epidiolex.com/about-epidiolex/story

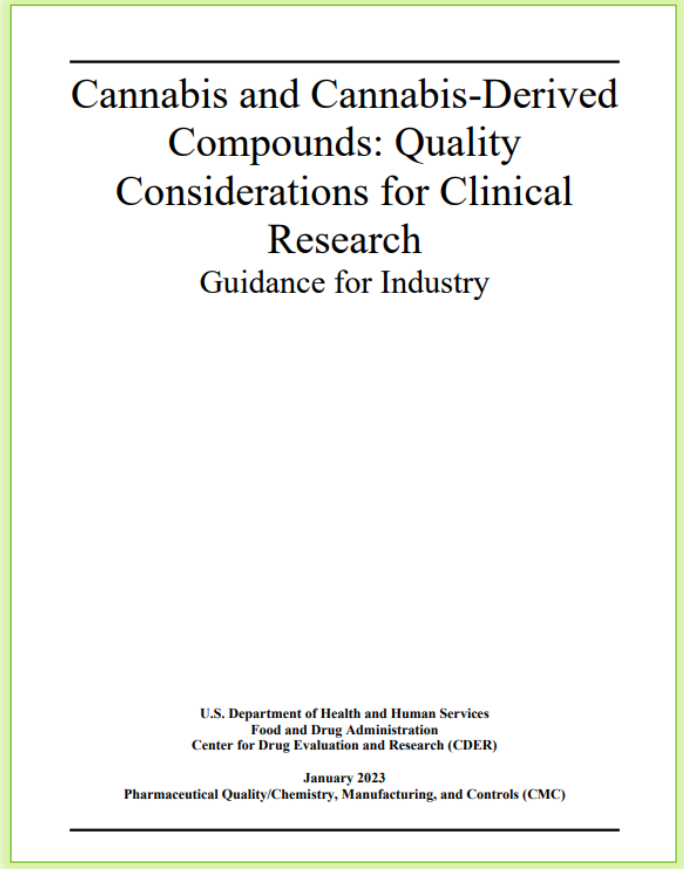
Cannabis Therapeutic Research Areas

- Over last 50 years, >800 INDs submitted
  - In first 40 years, FDA received over 400 submission
  - In last 10 years, received nearly 400 submission
  - Dramatic increase in submissions
- Nearly 150 active INDs



Cannabis Drug Development Final Guidance

- On January 24th, 2023 FDA published Final Guidance Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research
- Cannabis and cannabis-derived compounds can be used in clinical research
  - Under an Investigational New Drug (IND) application to study a specific therapeutic indication



- Sources of Cannabis
- Resources for Information on Quality Considerations
- Considerations of Control Status Under the CSA

SURVEILLANCE OF ADVERSE EVENTS

Consumer Update: Delta-8 THC

5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC

1. Delta-8 THC products have not been evaluated or approved by the FDA for safe use and may be marketed in ways that put the public health at risk.

2. The FDA has received adverse event reports involving delta-8 THC-containing products.

3. Delta-8 THC has psychoactive and intoxicating effects.

4. Delta-8 THC products often involve use of potentially harmful chemicals to create the concentrations of delta-8 THC claimed in the marketplace.

5. Delta-8 THC products should be kept out of the reach of children and pets.

For more information about Delta-8 THC: CDC HEALTH ALERT NETWORK (HAN)

Consumer Update: Delta-8 THC

5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC

2. The FDA has received adverse event reports involving delta-8 THC-containing products.

The FDA received 104 reports of adverse events in patients who consumed delta-8 THC products between December 1, 2020, and February 28, 2022. Of these 104 adverse event reports:

- 77% involved adults, 8% involved pediatric patients less than 18 years of age, and 15% did not report age.
- 55% required intervention (e.g., evaluation by emergency medical services) or hospital admission.
- 66% described adverse events after ingestion of delta-8 THC-containing food products (e.g., brownies, gummies).
- Adverse events included, but were not limited to: hallucinations, vomiting, tremor, anxiety, dizziness, confusion, and loss of consciousness.

National poison control centers received 2,362 exposure cases of delta-8 THC products between January 1, 2021 (i.e., date that delta-8 THC product code was added to database), and February 28, 2022. Of the 2,362 exposure cases:

- 58% involved adults, 41% involved pediatric patients less than 18 years of age, and 1% did not report age.
- 40% involved unintentional exposure to delta-8 THC and 82% of these unintentional exposures affected pediatric patients.
- 70% required health care facility evaluation, of which 8% resulted in admission to a critical care unit; 45% of patients requiring health care facility evaluation were pediatric patients.
- One pediatric case was coded with a medical outcome of *death*.

CHECK WEBSITE OFTEN FOR UPDATES

Warning Letters

- Warning Letters and Test Results for CBD-Related Products

Warning Letters and Test Results for Cannabidiol-Related Products

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Over the past several years, FDA has issued several warning letters to firms that market unapproved new drugs that allegedly contain cannabidiol (CBD). As part of these actions, FDA has tested the chemical content of cannabinoid compounds in some of the products, and many were found to not contain the levels of CBD they claimed to contain. It is important to note that these products are not approved by FDA for the diagnosis, cure, mitigation, treatment, or prevention of any disease. Consumers should beware purchasing and using any such products.

Content current as of:
02/01/2023

2023 Warning Letters

Firm	State	Purchase Website
Purecraft LLC	CA	https://purecraftcbd.com/
Medical Mikes, Inc.	NY	https://medicalmikes.com/
PharmaCanna	FL	https://www.pharmacanna.com

2022 Warning Letters

Firm	State	Purchase Website
Thriftmaster Global Holdings, Inc.	TX	www.thriftmasterholdings.com
11-11-11 Brands	PA	www.mood33.com
Naturally Infused LLC	FL	www.NaturallyInfused.com
CBD American Shaman, LLC	MO	www.cbdamericanshaman.com
Newhere Inc dba CBDFX	CA	www.CBDfx.com
Infusionz, LLC	NV	www.cbdinfusionz.com
Alternative Health Distribution LLC d/b/a CannaAid	NC	https://www.cannaaidshop.com
FluxxLab LLC	CO	https://fluxxlab.com/
H2 Beverages, Inc.	TX	https://h2bev.com
Young Living Essential Oils Corporate	UT	www.youngliving.com and https://naturesultra.com
New Sun Inc.	NC	www.mynewsun.com
Haniel Concepts, Inc. DBA Free State Oils, LLC	KS	www.freestateoils.com
Plantacea, LLC dba Kahm	NV	https://kahmcbd.com/
Hope Botanicals, LLC	TX	https://hopebotanicals.com
Ironmag Labs	NV	https://ironmaglabs.com
ATLRx Inc	GA	www.atlrx.com
BioMD Plus LLC	GA	www.biomdplus.com
Delta 8 Hemp	CA	https://delta8thc.market/
Kingdom Harvest LLC	NC	www.kingdomharvest.com
M Six Labs Inc.	WI	https://m6labs.com
Cureganics	CA	https://www.cureganics.com/

Warning Letters: Delta-8 THC

- News Release: [FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products](#) (05/04/2022)

FDA NEWS RELEASE

FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products

Violations Include Marketing Unapproved New Drugs, Misbranding, Adding Delta-8 THC to Food Products

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For Immediate Release: May 04, 2022

Content current as of: 05/04/2022

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Today, the U.S. Food and Drug Administration issued warning letters to five companies for selling products labeled as containing delta-8 tetrahydrocannabinol (delta-8 THC) in ways that violate the Federal Food, Drug, and Cosmetic Act (FD&C Act). This action is the first time the FDA has issued warning letters for products containing delta-8 THC. Delta-8 THC has psychoactive and intoxicating effects and may be dangerous to consumers. The FDA has received reports of adverse events experienced by patients who have consumed these products.

There are no FDA-approved drugs containing delta-8 THC. Any delta-8 THC product claiming to diagnose, cure, mitigate, treat, or prevent diseases is considered an unapproved new drug. The FDA has not evaluated whether these unapproved drug products are effective for the uses manufacturers claim, what an appropriate dose might be, how they could interact with FDA-approved drugs or other products, or whether they have dangerous side effects or other safety concerns.

Delta-8 THC is one of over 100 cannabinoids produced in the *Cannabis sativa* L. plant but is not found naturally in significant amounts. Concentrated amounts of delta-8 THC are typically manufactured from hemp-derived cannabidiol (CBD) and have psychoactive and intoxicating effects. Products containing delta-8-THC are available in varying forms, including but not limited to candy, cookies, breakfast cereal, chocolate, gummies, vape cartridges (carts), dabs, shatter, smokable hemp sprayed with delta-8-THC extract, distillate, tinctures, and infused beverages.

In addition to the violations related to FDA-regulated products containing delta-8 THC, several of the warning letters outline additional violations of the FD&C Act, including marketing CBD products claiming to treat medical conditions in humans and animals, promoting CBD products as dietary supplements, and adding CBD to human and animal foods. CBD and delta-8 THC are unapproved food additives for use in any human or animal food product, as the FDA is not aware of any basis to conclude that the substances are generally recognized as safe (GRAS) or otherwise exempt from food additive requirements. One of the letters expresses concerns regarding CBD products marketed for food-producing animals, and the potential safety concerns related to human food products (e.g., meat, milk, eggs) from animals that consume CBD, as there is a lack of data on safe CBD residue levels.

The FDA issued warning letters to:

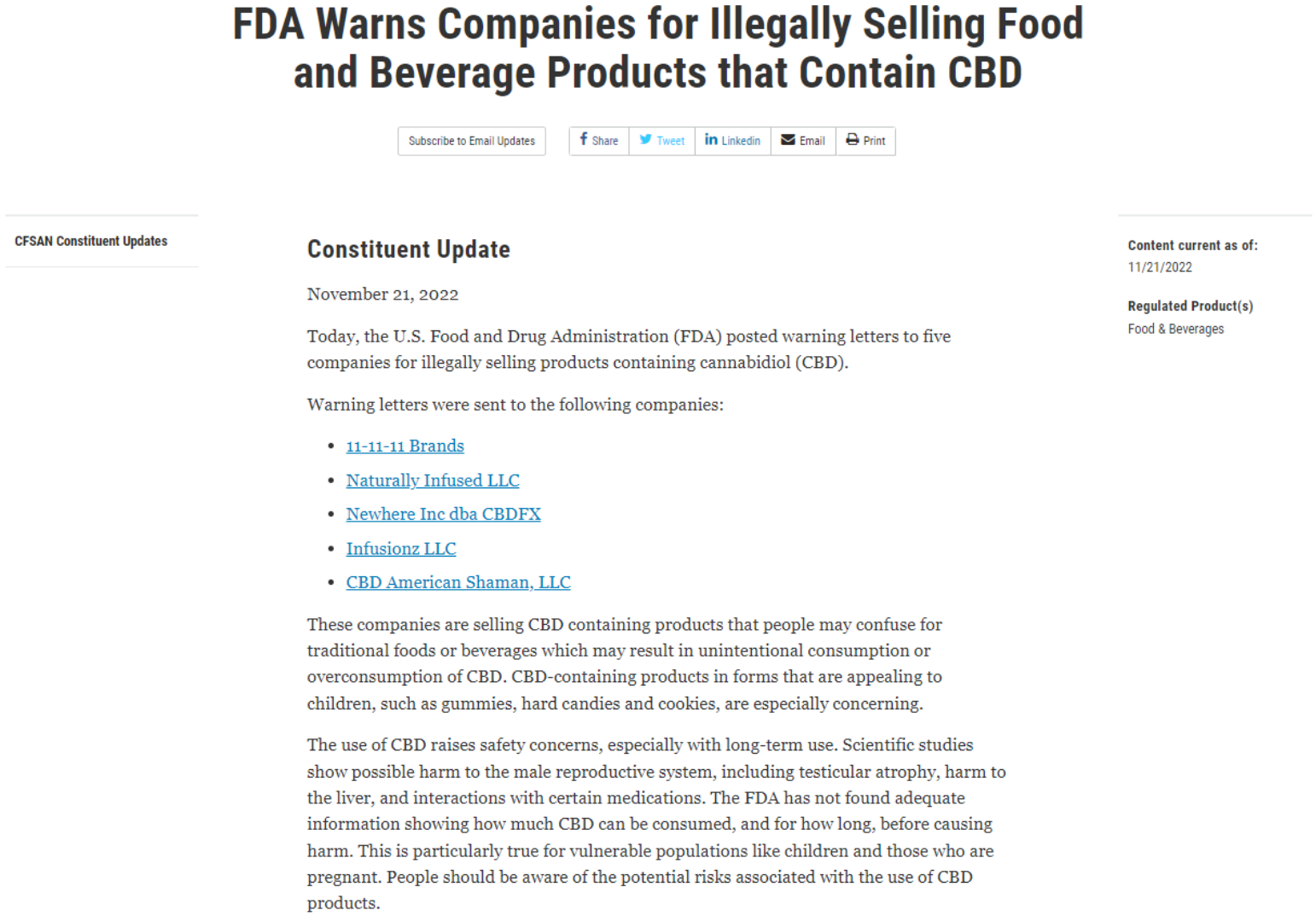
- ATLRx Inc.
- BioMD Plus LLC
- Delta 8 Hemp
- Kingdom Harvest LLC
- M Six Labs Inc.

The FDA has previously sent warning letters to other companies illegally selling unapproved CBD products that claimed to diagnose, cure, mitigate, treat or prevent various diseases, in violation of the FD&C Act. In some cases, there were further violations because CBD was added to food products. The FDA has not approved any CBD products other than one prescription human drug product to treat rare, severe forms of epilepsy.

The FDA has requested written responses from the companies within 15 working days stating how they will address these violations and prevent their recurrence. Failure to promptly address the violations may result in legal action, including product seizure and/or injunction.

Warning Letters: CBD

- FDA Warns Companies for Illegally Selling Food and Beverage Products that Contain CBD (11/21/2022)



FDA Warns Companies for Illegally Selling Food and Beverage Products that Contain CBD

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CFSAN Constituent Updates

Constituent Update

November 21, 2022

Today, the U.S. Food and Drug Administration (FDA) posted warning letters to five companies for illegally selling products containing cannabidiol (CBD).

Warning letters were sent to the following companies:

- 11-11-11 Brands
- Naturally Infused LLC
- Newhere Inc dba CBDFX
- Infusionz LLC
- CBD American Shaman, LLC

These companies are selling CBD containing products that people may confuse for traditional foods or beverages which may result in unintentional consumption or overconsumption of CBD. CBD-containing products in forms that are appealing to children, such as gummies, hard candies and cookies, are especially concerning.

The use of CBD raises safety concerns, especially with long-term use. Scientific studies show possible harm to the male reproductive system, including testicular atrophy, harm to the liver, and interactions with certain medications. The FDA has not found adequate information showing how much CBD can be consumed, and for how long, before causing harm. This is particularly true for vulnerable populations like children and those who are pregnant. People should be aware of the potential risks associated with the use of CBD products.

Content current as of:
11/21/2022

Regulated Product(s)
Food & Beverages

Consumer Warning: Accidental Ingestion of Foods Containing THC

FDA Warns Consumers About the Accidental Ingestion by Children of Food Products Containing THC

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May 13, 2022

Audience

- All consumers

What is the problem?

- Edible products containing tetrahydrocannabinol (THC) can be easily mistaken for commonly consumed foods such as breakfast cereal, candy, and cookies, and accidentally ingested.
- Accidental ingestion of these products can lead to serious adverse events, especially in children.
- Some edible products are designed to mimic the appearance of well-known branded foods by using similar brand names, logos, or pictures on their packaging. These copycats are easily mistaken for popular, well-recognized foods that appeal to children.
- The FDA is aware of reports of copycat products packaged to look like Cap'n Crunch, Cocoa Pebbles, Cocoa Puffs, Froot Loops, Fruity Pebbles, Nerds Ropes, Starbursts, Sour Patch Kids, and Trix, among others.

Examples of Products

Who is at risk?

The FDA is advising consumers about the risk of accidental ingestion, especially by children, of edible products that contain THC. Accidental ingestion of these edible products may cause serious adverse events.

Summary of Problem and Scope

Some manufacturers are packaging and labeling edible products containing THC to look like popular brands of commonly consumed foods, such as breakfast cereal, candy, and cookies. These products appeal to children and may be easily mistaken for popular, well-recognized foods.

The FDA is aware of multiple media reports describing children and adults who accidentally consumed copycat edible products containing THC and experienced adverse events. Additionally, from January 2021 through April 24, 2022, the FDA received over 100 adverse event reports related to children and adults who consumed edible products containing THC. Some individuals who ate these edible products reportedly experienced adverse events such as hallucinations, increased heart rate and vomiting, and many required medical intervention or hospital admission. Seven of the reports specifically mention the edible product to be a copycat of popular foods, such as Cocoa Pebbles, Nerds Rope, Skittles, Sour Patch Kids, and Starburst.

FDA Targeted Actions to Protect Public Health

FDA_ORA
@FDA_ORA

❗ ALERT: FDA recently forwarded a complaint re: a serious adverse event associated w/Wonky Confection's Death by Gummy Bears delta-8 THC product to the MN Board of Pharmacy, resulting in a state action against this firm. LEARN MORE: mn.gov/boards/pharmac...

6:09 PM · Dec 5, 2022

FDA_ORA @FDA_ORA · 1m
Replying to @FDA_ORA
Today's announcement from the MN Board of Pharmacy is an example of how the FDA is actively working w/its state partners to address risky products containing delta-8 THC & other cannabis derivatives. LEARN MORE: mn.gov/boards/pharmac...

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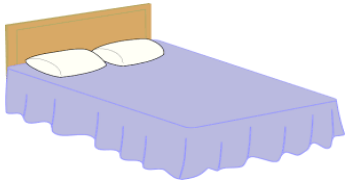
Cannabis Products Are Everywhere

Foods

Drugs

Cosmetics

Dietary Supplements



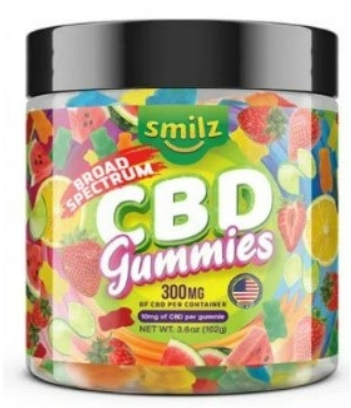
Clothing and Bedding

Animal Health Products

Image source: www.clipart-libary.com

Cannabis Products Are Everywhere

Examples of CBD products targeting or appealing to children or with risky routes of administration (eye drops, injection, and nasal spray)



Examples of intoxicating hemp products

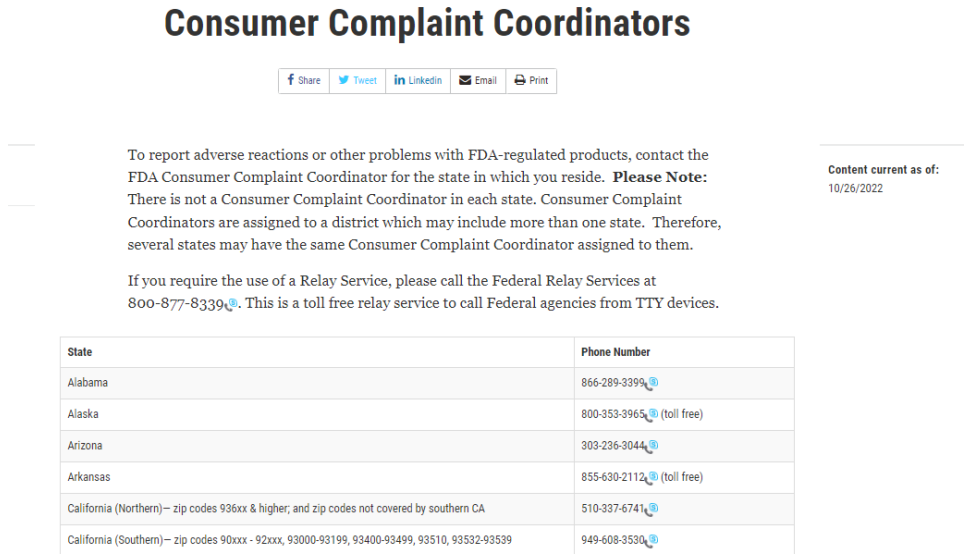
Reporting Safety Concerns to FDA

Food and Drug Administration

MedWatch

Link to MedWatch

Link to Safety Reporting Portal



Consumer Complaint Coordinators

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To report adverse reactions or other problems with FDA-regulated products, contact the FDA Consumer Complaint Coordinator for the state in which you reside. **Please Note:** There is not a Consumer Complaint Coordinator in each state. Consumer Complaint Coordinators are assigned to a district which may include more than one state. Therefore, several states may have the same Consumer Complaint Coordinator assigned to them.

If you require the use of a Relay Service, please call the Federal Relay Services at 800-877-8339. This is a toll free relay service to call Federal agencies from TTY devices.

Content current as of: 10/26/2022

State	Phone Number
Alabama	866-289-3399
Alaska	800-353-3965 (toll free)
Arizona	303-236-3044
Arkansas	855-630-2112 (toll free)
California (Northern)– zip codes 936xx & higher; and zip codes not covered by southern CA	510-337-6741
California (Southern)– zip codes 90xxx - 92xxx, 93000-93199, 93400-93499, 93510, 93532-93539	949-608-3530

Link to Consumer Complaint Coordinators

How to Report to MedWatch

- Online (www.fda.gov/medwatch)
  - Use the interactive form at FDA Form 3500
  - FDA **encourages online** reporting because it is quickest and most direct route

- Download the form above
  - Mail
  - Fax 1–800–332–0178

- Call FDA
  - 1-800-FDA-1088
  - Monday - Friday 8AM – 4:30 PM EST

- Different forms
  - Health professional: Form 3500
  - Consumer: Form 3500B
- 4 primary components needed
  - **Patient, product, event, reporter**

MedWatch Reporting

MedWatch: The FDA Safety Information and Adverse Event Reporting Program

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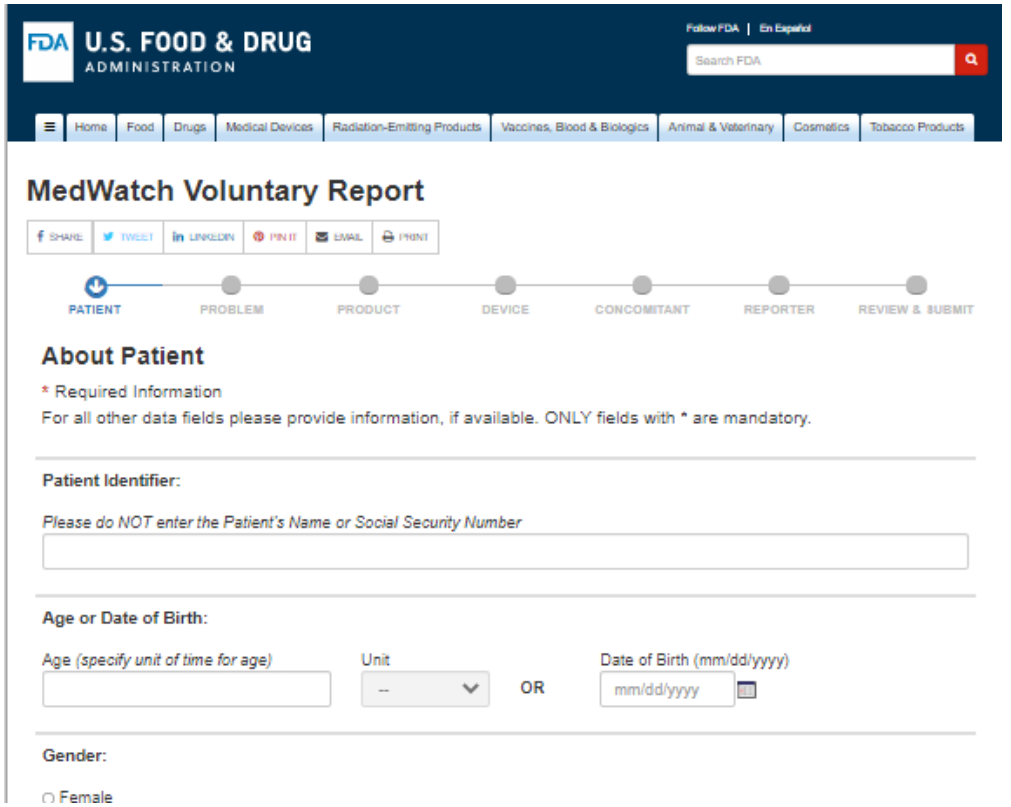
MedWatch, the FDA's medical product safety reporting program for health professionals, patients and consumers.

Report a Problem | Safety Information | Stay Informed

1. Patient
2. Product
3. Event
4. Reporter



Components of a Good Report

- Description of adverse event
- **Suspected product information (e.g., manufacturer, product name, formulation, lot number, place of purchase, product pictures or website, dosage, dates of therapy, reason for use)**
- Concomitant medication information
- Patient characteristics (e.g., age, sex), baseline medical condition, co-morbid condition
- Documentation of the diagnosis
- Clinical course and outcomes
- Relevant therapeutic measures and laboratory data
- Dechallenge and rechallenge information
- Reporter contact information

What Does FDA Do With The Reports

- Reviewers evaluate reported information
  - Safety information of interest to reviewers during surveillance includes:
    - Serious adverse events (death, life-threatening, hospitalization, disability, congenital anomaly, other/required intervention)
    - Unexpected adverse events
    - Product specific concerns
    - Drug interactions
    - Adverse events reported in a specific patient population
    - Trends
- Analysis assists in determining safety issues

Summary and Conclusions

- FDA has a well-defined role to play in the regulation and development of products containing cannabis and cannabis-derived compounds, and FDA will continue to protect and promote the public health with respect to these products.

- FDA continues to focus on supporting scientific and rigorous testing and approval of drugs derived from cannabis and supporting **robust scientific research** into understanding **therapeutic uses and safety** of non-drug cannabis products.

- FDA is actively exploring potential **regulatory pathways** for the **lawful marketing** of appropriate cannabis-derived products.

- FDA is **committed to protect and promote the public health** with respect to products containing cannabis and cannabis-derived compounds, including enforcement action when needed.

- FDA has **only approved** one cannabis-derived and three cannabis-related drug products.

CLINICIAN PERSPECTIVE

Clinical Perspective

- Insights from Dr. Gioia Guerrieri
  - Board-certified in psychiatry and addiction medicine
    - Fellowship subspecialty in reproductive psychiatry
  - Full-time Medical Officer at FDA in addiction medicine
  - Opened her outpatient private practice in 2013
    - Women's Behavioral Health and Adult Psychiatry
  - Distinguished Fellow of the American Psychiatry Association
  - Member, American College of Psychiatrists

Highlights for HCPs

- Gain understanding on the products your patients are using
  - Names of products
  - List of ingredients (e.g., CBD, delta-9 THC, delta-8 THC, HHC, THCO-A, etc.)
  - Points of sale (e.g., dispensary, convenient store, gas station, online, etc.)
  - Reasons for use (e.g., stress, sleep aid, relaxation, replacing Rx products, etc.)

- Create safe space for your patients to discuss their cannabis product use
  - Help to reduce stigma
  - Discuss importance of storing products out of reach from children and pets

- Ask patients about dosing and frequency of use
  - ROAs, strength, potency
  - Co-use with prescriptions, dietary supplements, other substances

- Remind patients about cannabis products in the marketplace
  - Except for 4 FDA approved drugs, products are not FDA-approved or evaluated by FDA for safety and efficacy
  - Manufacturing and quality controls vary greatly

- Report Adverse Events to FDA
  - MedWatch

Free Resources for HCPs

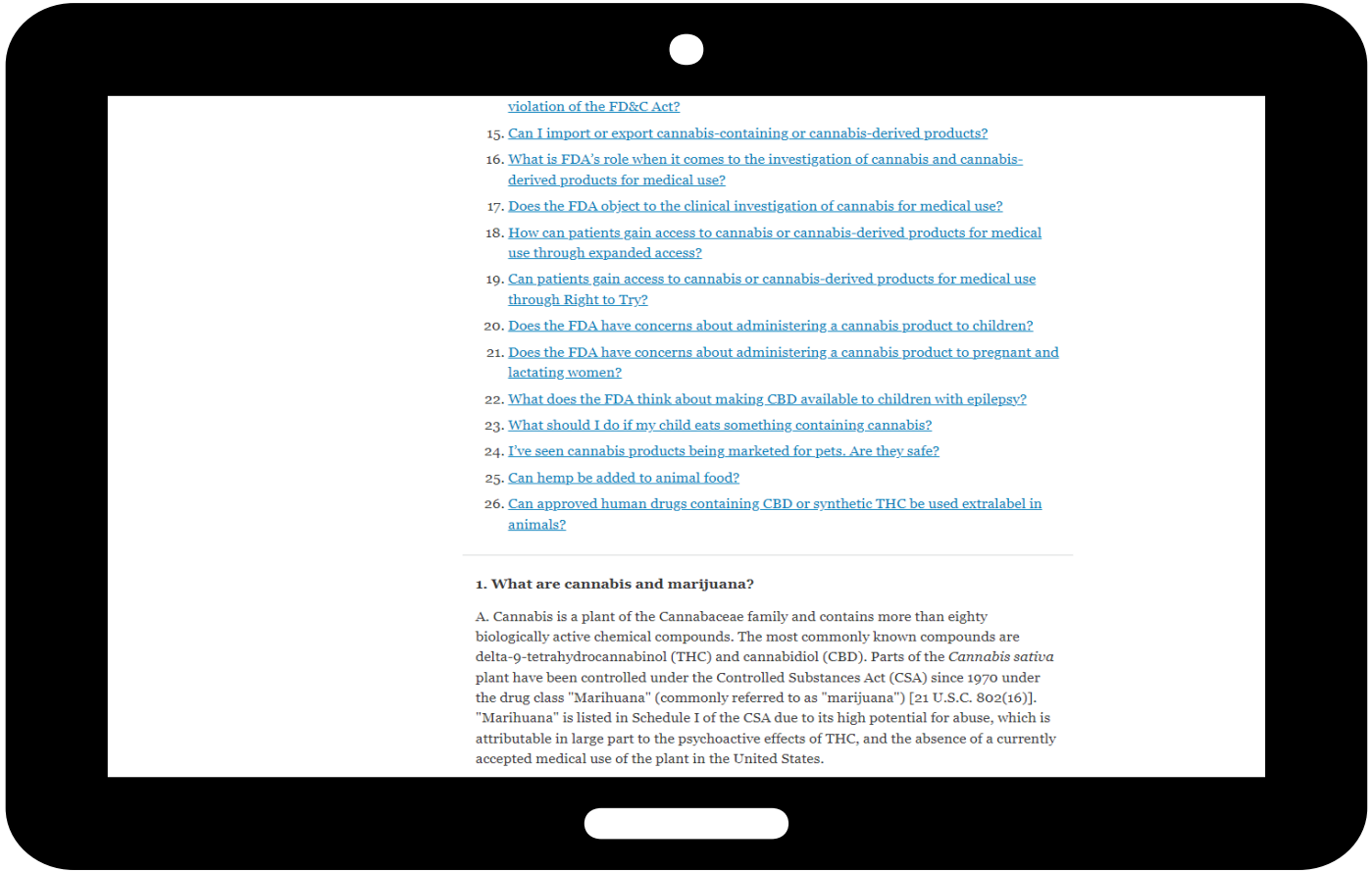
- SAMHSA Resources:
  - 200 page Counseling Manual – "Brief Counseling for Marijuana Dependence"
  - Overview of Motivational Interviewing – "Using Motivational Interviewing in Substance Use Disorder Treatment"
  - Infographic to Hang in Office – "Marijuana: The Risks Are Real"
  - Information on Risks of Use – "Learn About Marijuana Risks"
  - 60-second Videos from SAMHSA
    - "Marijuana Use while Pregnant or Breastfeeding" – avoiding marijuana can give baby a healthier start in life
    - "Build a Brain" – visuals on how marijuana can impact adult memory, brain development, & concentration
    - "Virtual Assistant" – marijuana risks through lighthearted conversation, appealing to young adult audience
- CDC Resources:
  - Addiction (Marijuana or Cannabis Use Disorder)
  - Marijuana and Public Health

FDA Resources

FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)

On this page:

- FDA New Releases and Statements
- Consumer Information
- FDA Remarks and Testimony
- Science & Research
- Other Regulatory Resources
- Questions and Answers



References

- FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)
- FDA and Cannabis: Research and Drug Approval Process
- Guidance for Industry Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research (January 2023)
- FDA Regulation and Quality Considerations for Cannabis and Cannabis-Derived Compounds – Chronicles article and Podcast
- FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward
- June 14, 2022 Meeting of the Science Board to the FDA

Thank You


FDA
U.S. FOOD & DRUG
ADMINISTRATION