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# FDA Policy and Pathway for Cannabidiol (CBD) in Foods

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# Relationship Between Marijuana and Hemp

Botanical Distinctions

Cannabinoids: THC, CBD, and Others

Overview of Hemp-Derived Ingredients

# Hemp versus Marijuana

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- *Cannabis Sativa L.* is the genus and species of plant that can refer to either industrial hemp or marijuana



# Hemp versus Marijuana

## Botanical and Legal Differences

- Botanical
  - Hemp:
    - Grown for fibrous stalks/maximize height
    - Generally lower cannabinoid content
  - Marijuana:
    - Grown to maximize THC content/shorter plants with more leaf density
    - Generally higher cannabinoid content

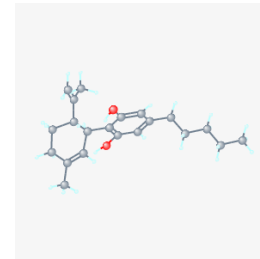
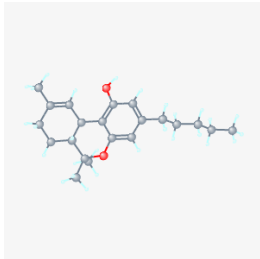


# Cannabinoids

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## THC, CBD, and many more

- Over 100 different cannabinoids have been isolated from the Cannabis plant.
- Delta-9 tetrahydrocannabinol (THC)
  - Responsible for “high” or intoxicating effects of marijuana.
- Cannabidiol (CBD)
  - Non-intoxicating, does not produce “high” associated with delta-9 THC.
  - Approved by FDA in June 2018 as a drug (Epidiolex) to treat seizures related to two rare, severe forms of epilepsy.



# Hemp-Derived Ingredients Generally

- Hemp-derivatives for human/animal consumption or topical use
  - Hemp seed
  - Hemp seed protein powder – typically made from grinding hemp seeds into powder
  - Hemp seed oil/ Cannabis sativa seed oil – oil extracted from hemp seed
  - Hemp oil/ Cannabis sativa oil/“Full spectrum hemp oil” – oil extracted from the entire hemp plant (or portions of the hemp plant other than seeds)
  - CBD/CBD Oil – could refer to hemp oil, or CBD isolated from hemp oil
- Note these terms are not used consistently in the marketplace
  - For now, GRAS notices for dehulled hemp seeds, hemp seed protein powder, hemp seed oil provide some insight on appropriate ingredient naming



# What the Farm Bill Changes

Controlled Substances Act Definitions of Marijuana and THC

Regulation of Domestic Cultivation of Hemp

# Federal Controlled Substances Act

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## Schedule I (OLD DEFINITION)

- Marijuana
  - “The term “marihuana” means all parts of the **plant *Cannabis sativa L.***, whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. **Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.”**
    - *21 USC 802(16) (pre-2018 Farm Bill).*
      - 2018 Farm Bill adds an exclusion to the definition of marijuana for “hemp.”
  - Confusingly, under the old definition, the part of the plant dictated the difference between hemp and marijuana—buds and leaves would fall within definition of marijuana



# 2018 Farm Bill Revisions to CSA

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- Any part of the *Cannabis sativa L.* plant with less than 0.3% THC on a dry weight basis is “hemp”
- “Hemp” is now exempt from definition of “marijuana” in CSA
- THC in “hemp” also exempt from definition of “THC” in CSA

**“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.”**

*Agricultural Marketing Act of  
1946, Section 297A, as amended  
by 2018 Farm Bill*

# 2018 Farm Bill and Domestic Cultivation of Hemp

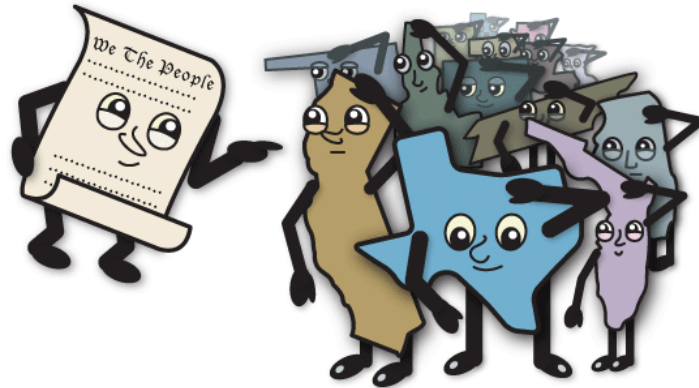
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- Reduces limitations on cultivation of hemp in U.S.
  - 2018 Farm Bill explicitly allows commercial sale of hemp and hemp-derived products
- 2018 Farm Bill allows states to decide whether to take primary regulatory authority over cultivation of hemp in that state
  - State can submit plan to regulate hemp to USDA for approval
  - If state does not develop program, cultivation of hemp in the state will be subject to regulation under plan developed by USDA
- State and USDA plans need to address testing and compliance, enforcement standards
  - Will take time to establish these programs and cultivate hemp in accordance with these programs

# 2018 Farm Bill and Interstate Commerce

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- “Nothing in this title or an amendment made by this title prohibits the interstate commerce of hemp (as defined in Section 297A of the Agricultural Marketing Act)...or hemp products.”
- “No state...shall prohibit the transportation or shipment of hemp or hemp products produced in accordance with subtitle G of the Agricultural Marketing Act of 1946...through the state.”



# Status of Hemp Cultivation Plans

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- State Plans
    - KY submitted [plan](#) to USDA on December 20, 2018
    - PA submitted plan to USDA on January 22, 2019
    - Other states that did not have existing hemp programs (under 2014 Farm Bill) have begun introducing legislation to regulate hemp production in the state. See for example Georgia, [HB-213, Georgia Hemp Farming Act](#)
  - No USDA approvals of any state plans yet.
  - 60 day review period; but also need to account for government shutdown (35 days).
- USDA Plan
    - USDA-AMS issued Notice to Trade stating the agency will not review state plans until after USDA promulgates its own regulations.  
<https://www.ams.usda.gov/content/hemp-production-program>
    - USDA intends to issue regulations in Fall 2019 for the 2020 growing season
    - In the interim, USDA has reiterated that hemp activities can continue under authority of 2014 Farm Bill
      - But 2014 Farm Bill does not allow hemp cultivation for general commercial activity, only for purposes of marketing research
    - Senators McConnell and Wyden sent letter to USDA Secretary Perdue asking USDA to move forward “expeditiously” and issuing guidance when necessary to “minimize any interference with the lawful transportation of hemp products.”  
<https://senmccconnell.app.box.com/s/9bu1v2jmoybdinj1z7kip8x3y91450qo>

# What the 2018 Farm Bill Does NOT Change

FDA's Authority Over Drugs, Foods, Dietary Supplements, and Cosmetics

# 2018 Farm Bill Does Not Amend FDA's Authority

- 2018 Farm Bill contains provision that nothing in the law affects or amends FDA's authority under the Federal Food, Drug, and Cosmetic Act (FFDCA).
- To the extent hemp or hemp-derived ingredients are used in an FDA-regulated product, subject to FDA's regulatory authority, which is unchanged by 2018 Farm Bill.



# CBD in Foods and Dietary Supplements

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- FDA approved CBD as drug in June 2018 (Epidiolex)
  - Drug approval limited to Epidiolex; not applicable to CBD generally.
- FDA has taken position CBD is not a lawful food or dietary supplement ingredient, whether derived from hemp or marijuana under the exclusionary clauses of FFDCA:
  - A substance approved as a drug or which is the subject of substantial clinical investigations that have been made public may not be used in a food or dietary supplement unless the substance was first marketed in a food or dietary supplement prior to FDA issuance of the IND.
- FDA has concluded the “first marketed as” exemption does not apply
- First Issue: Must demonstrate marketing of CBD or foods or dietary supplements for their CBD content PRIOR to FDA authorization of the IND



# Which Was #1?

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- Must be able to demonstrate:
  1. Marketing of CBD as a food or dietary supplement; or
  2. Marketing of a hemp ingredient for its CBD content prior to FDA issuance of the IND
- What type of data?
  1. Published articles
  2. Advertisements
  3. Sales catalogs
  4. Website sales
- Does product have to be a lawfully marketed substance at the time?





# CBD in Foods or Dietary Supplements

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- In the event a company can demonstrate marketing of CBD first as a food or dietary supplement, the company must then comply with the premarket authorization requirements
- Foods
  - Must be approved food additive or GRAS
  - Are there sufficient data in the public domain to support the GRAS status of CBD?
- Dietary Ingredients
  - CBD is likely a new dietary ingredient unless it was marketed as a dietary supplement prior to October 1994
  - New dietary ingredients are exempt from the premarket notification requirements if present in the food supply in a form that has not been chemically altered



# Hemp-Derived Ingredients as a Food or Dietary Supplement

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- FDA Response to GRAS Notices for dehulled hemp seeds, hemp seed protein, hemp seed oil:
  - “No questions” regarding conclusions these ingredients are GRAS under intended conditions of use
  - Low THC hemp seeds sourced from Canada
  - Specifications for THC content
  - No specifications for CBD content
- These “GRAS” hemp-derived ingredients can be marketed as ingredients in foods and dietary supplements

# FDA Reaction to 2018 Farm Bill

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- Commissioner Gottlieb issued statement reiterating FDA position that exclusionary clause prohibits use of CBD in food.
- FDA remains concerned about number of CBD-containing products bearing unapproved drug claims.
  - Will continue to closely scrutinize products that could pose risks to consumers.
- Commissioner Gottlieb acknowledged FDA could initiate rulemaking to overcome the exclusionary clause (*i.e.*, food additive petition for CBD).
  - Agency considering whether to pursue such an action
  - On April 2, FDA announced it will hold a public meeting on CBD on May 31, 2019
    - FDA raises number of questions to consider during meeting in FR notice, including regarding safety, manufacturing, labeling for variety of product forms

# Congressional Intent and CBD

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- On January 15, Senators Wyden and Merkley (OR) sent letter to FDA Commissioner Gottlieb regarding the intent of the Hemp Farming Act with respect to hemp-derived CBD in foods, beverages, and dietary supplements.
- “Current, outdated regulations limit producers from taking full advantage of the industrial hemp market by, for example, prohibiting food products containing CBD from being sold across state lines . . . We therefore request the FDA immediately begin updating regulations for hemp-derived CBD and other hemp-derived cannabinoids, and give U.S. producers more flexibility in the production, consumption, and sale of hemp products.”

– <https://www.wyden.senate.gov/imo/media/doc/011519%20FDA%20CBD%20Hemp%20Letter.pdf>

# State Regulation of CBD and Hemp-Derived Ingredients

Case studies: California, Washington, Colorado

State Enforcement Actions

# State Laws on Hemp-Derived Ingredients

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- Some states have amended laws to address use of CBD in food/dietary supplements.
  - Common misconception to assume that because a state has authorized recreational marijuana it will allow use of CBD in food/dietary supplements.
- Majority of states haven't addressed use of CBD in food/supplements
  - Some states have access programs to CBD oil for medicinal use.
- Some state controlled substances acts may use different definitions than federal act and not provide the same exemption from control for hemp.
- Regardless of state law, FDA's position on CBD in food/supplements still applies to products in interstate commerce.
  - Very difficult to have purely "intrastate" product and should assume FDA could assert jurisdiction over foods/supplements containing CBD.

# State Enforcement Against CBD-Containing Foods

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- A number of states have taken enforcement action against CBD-containing foods and supplements citing FDA's position that CBD is prohibited from use in these products.
  - New York City Department of Health and Mental Hygiene seized CBD-containing foods from restaurants
  - North Carolina Department of Agriculture began sending Warning Letters to businesses selling CBD-infused foods and beverages
- Other states have issued guidance stating that CBD is prohibited from use in food
  - Ohio Board of Pharmacy issued FAQs explaining CBD is considered marijuana under state law and not a lawful food ingredient

# State Law Takeaways

- Don't assume states that have legalized recreational marijuana allow CBD/hemp-derived ingredients in food.
- Many states have not explicitly addressed issue. Other states considering legislation now, a very quickly developing area.
- States may be more active/different in enforcement than FDA.

Business/Economy

## Want some CBD in your coffee? Marijuana-linked oil raises concerns among regulators

Author: Annie Zak Updated: December 19, 2018 Published December 19, 2018



<https://www.adn.com/business-economy/2018/12/19/want-some-cbd-in-your-coffee-marijuana-linked-oil-raises-concerns-among-regulators/>



# Summary

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- 2018 Farm Bill clarified legal distinction between hemp and marijuana, made clear “hemp” is not Schedule I controlled substance.
- USDA/state hemp cultivation programs need to be developed to source hemp domestically in accordance with the 2018 Farm Bill.
- CBD and other hemp derivatives not “legal” in the sense still subject to regulatory authority of FDA in drugs, foods, dietary supplements, cosmetics.
- Have to consider status of CBD/hemp derived ingredients under state law as well.
- Work with FDA/controlled substances regulatory counsel to navigate these issues.

# Questions?

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# Presenter

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