



CBD: Legal Landscape for Animal Products

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Agenda

- Overview of CBD
 - Marijuana vs. Hemp vs. CBD
 - Who Regulates CBD?
 - State Level Regulation
 - The 2018 Farm Bill
 - CBD Takeaways & Recent Developments
- Animal Products: Recent Enforcement Actions & Industry Takeaways
 - FDA Enforcement
 - FTC Enforcement
 - State-Level Enforcement
- Questions

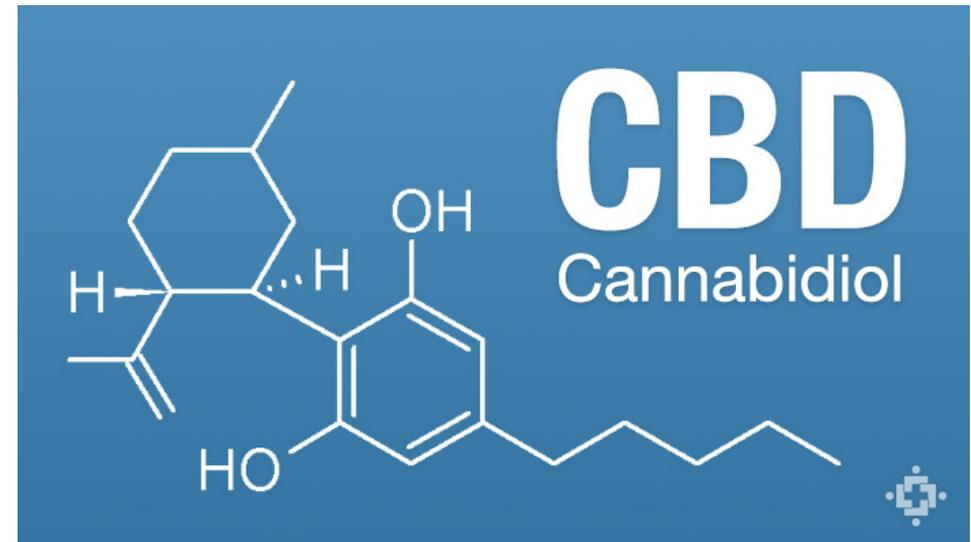
Plant Background: Marijuana vs. Hemp

- *Cannabis sativa L.*: A plant species that is part of a genus of flowering plants called “Cannabis”
 - Varieties include **both** marijuana and hemp
- Marijuana
 - Contains over 0.3% THC (tetrahydrocannabinol)
 - Considered a Schedule I controlled substance under federal law
- Hemp
 - Cannabis plant *not* used as a drug
 - Generally, grown for use in food, dietary supplements, fabrics, textiles, etc.



Plant Background: What Is CBD?

- One of many cannabinoids found in the *Cannabis sativa* plant
- Non-mind-altering compound
- Contains negligible amounts of THC



Plant Background: Terpenes

- Class of organic compounds produced by many plants
- More than 100 in cannabis plants
- Responsible for aroma & taste
- Synergy of cannabinoids and terpenes



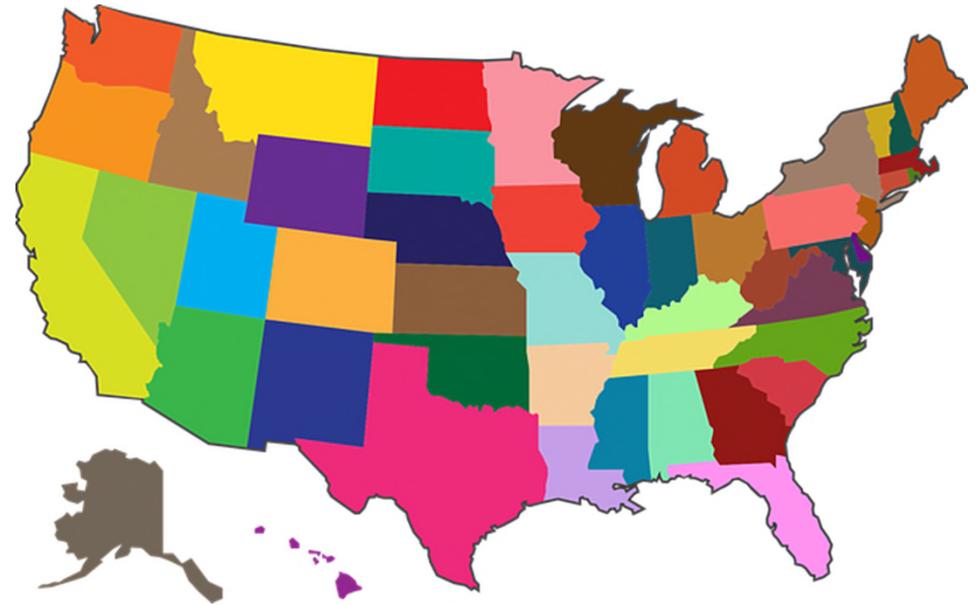
Plant Background: Federal Regulators of CBD

	FDA	FTC	DEA	USDA
Legal Authorities	<u>Federal Food, Drug & Cosmetic Act (FDCA)</u> Misbranding Adulteration	<u>Federal Trade Commission Act</u> False and Misleading Advertising Deceptive Marketing Practices	<u>Controlled Substances Act</u>	<u>2018 Farm Bill</u>
Issues	Label Format and Content Claims & Intended Use Manufacturing & Quality Assurance Ingredients / Product Safety	Express and Implied Claims Substantiation Endorsements & Testimonials Online Marketing (Payment terms, privacy disclosures, data security, etc.)	Manufacturing, Distribution, and Advertising of Controlled Substances	Growth, Cultivation, and Licensure of Hemp*
Investigative Tools	Inspections / 483s Warning Letters Import Detention	Civil Investigative Demands	Inspections, Warning Letters, and Investigations	Inspections and Crop Testing*
Enforcement	Product Seizures Injunctions Civil/Criminal Penalties	Asset Freezes Temporary Restraining Orders / Injunctions Civil Litigation	Criminal/Civil Penalties	Varies at State Level*

*USDA reviews and approves hemp programs; states set own rules on hemp crop testing.

Plant Background: Who Regulates CBD?

- Various State-Level Agencies
 - State Attorneys General
 - State Departments of Agriculture
 - State Departments of Health
 - State Boards of Pharmacy/Veterinary Medicine
- State-to-state differences on regulations, licensure processes, testing requirements, etc.
- Association of American Feed Control Officials (AAFCO), as a voluntary organization of regulatory officials



2018 Farm Bill: What it Did

- Agriculture Improvement Act of 2018 (the “2018 Farm Bill”)
 - **Signed into law December 20, 2018**
 - Removed hemp and all its derivatives from the federal definition of marijuana; defined as any cannabis plant with no more than 0.3% THC
 - Established USDA as the regulator for hemp as an agricultural commodity



2018 Farm Bill: Industrial Hemp Programs

- Under the 2018 Farm Bill, states are allowed to seek USDA approval for hemp cultivation and research programs
 - States can allow cultivation, domestic import/export, and processing of hemp
 - States may opt to take part in a USDA-run industrial hemp program
 - All hemp must not exceed 0.3% THC by weight



Key Takeaways

- The Farm Bill **did**:
 - Remove “hemp” as a controlled substance
 - Establish a pathway for USDA and state-regulated “hemp production”
 - Repeal of “industrial hemp research” provision at 7 U.S.C. § 5940 one year after Dept. of Ag. Regulatory scheme is established

- The Farm Bill **did not**:
 - Legalize marijuana or marijuana-derived CBD
 - Change FDA’s authority over cannabis derivatives, including animal feed and animal drugs
 - Preempt state laws prohibiting Industrial Hemp

FDA Developments

- Recognizing that the 2018 Farm Bill paved the way for CBD use in consumer products, FDA is currently evaluating a range of CBD issues
- 2019
 - May 31, 2019 hearing: FDA discussed safety risks of CBD use (e.g., cumulative exposure, adverse events, drug interactions, use by vulnerable populations), unclear industry definitions for CBD, and issues relating to CBD production and quality
 - Various public statements from FDA reflecting hesitancy about CBD safety, including potential risks in animal feed and to animals

Recent Developments

■ 2020

- FDA issued a press release and congressional report on its current CBD stance
- Largely echoes concerns raised in 2019; FDA is still aware of the large consumer interest in CBD, but is concerned about public perceptions that all CBD products on the market are safe
- FDA identified a series of CBD “knowledge gaps” (e.g., effects of sustained use, purity of CBD in the marketplace, CBD absorption pathways)
- Reopened its docket to collect CBD information indefinitely
- Indicated an enforcement policy may be forthcoming
- Seeking information to distinguish “broad”/ “full” spectrum & isolates

CBD & Animal Products

- FDA is aware that separate from human products, there is a growing market for CBD-containing products marketed for pets and other animals
- Currently, FDA has **not** approved CBD for **any use** in animals
 - The agency notes that its concerns regarding CBD products with unproved medical claims and unknown quality/composition for *human products* apply equally to *animal products*



AAFCO Position

- The Association of American Feed Control Officials (AAFCO) is a voluntary membership association of local, state and federal agencies, who are charged to regulate animal feeds and animal drug
- As of May 2019, AAFCO's Guidelines on Hemp in Animal Food provide that hemp and hemp products may **not** be used in animal feed or pet food in the United States noting the following:
 - *“...materials and products that are **CBD-infused need to be treated as drugs** because the intended uses are largely associated with drug claims. This means that parts of the hemp plant will not be appropriate for approval as an animal feed ingredient”*
 - *“[a]side from CBD, there are parts of the plant, such as **the hemp seeds, that have the potential be approved for animal feed**”*

AAFCO Position (cont.)

- Impact of AAFCO's Position on Animal Food Sales and Distribution
 - AAFCO Expects to review ***hemp seed oil, hemp seed cake meal***, and whole hemp seeds when industry completes safety reviews
 - Currently, takes the position that ***cannabinoids will be regulated as a drug*** because AAFCO believes is *no nutritional basis* for these compounds to be included in animal feed or pet food

Recent Enforcement Examples & Industry Takeaways



FDA Enforcement

- Recent wave of FDA Warning Letters regarding the use of aggressive claims on CBD-containing animal products
- Several of these companies are *located in states where marijuana sales and possession have been legalized*, including California and Colorado
- Two primary alleged violations:
 - **(1) adulterated animal food products because CBD as an ingredient or additive is not generally recognized as safe (GRAS) in animal feed**
 - **(2) unapproved new animal drugs, including reference to disease claims**
- FDA has raised concerns about safety, including noting that more information is particularly needed about use of CBD with animals and livestock that produced eggs, meat, and milk

FDA Enforcement

▪ Example Violative Claims

– Homero Corp. (April 10, 2020)

- “Works incredibly well for joint pain [and aggression] in pets,” “CBD oil works great for pets [with anxiety, hyperactivity, or PTSD]”

– Apex Hemp Oil LLC (November 22, 2019)

- “Adding [our CBD product can] help fight infection and inflammation,” “CBD Hemp Oil is recommended in [equine anxiety and arthritis]”

– Sunflora, Inc. (November 22, 2019)

- “CBD may calm dogs made frantic by fireworks,” “CBD stopped [my dog’s] anxiety,” “CBD [eases animal epilepsy]”

FTC Enforcement

- FTC has joined FDA in issuing several recent Warning Letters regarding CBD-containing animal products
 - Savvy Holistic Health (April 7, 2020)
 - Relievus, Inc. (March 28, 2019)
- In each letter, FTC notes concerns with the level of substantiation held by the advertiser and the agency's willingness to seek injunctive or monetary relief
- Beyond the four warning letters issued jointly with FDA, FTC independently issued warning letters to three companies albeit in human food context that sell oils, tinctures, capsules, “gummies,” and creams containing CBD

State-Level Enforcement

- Highly dependent on legal status of CBD and whether CBD is allowed in animal feed
- *Compare:*
 - Florida allows CBD in pet food and pet treats so long as they meet certain requirements
 - Oregon authorizes the manufacture, distribution and sale of Hemp-CBD pet foods, which are limited to “dog and cat” foods containing no more than 0.3 percent total THC
- *With:*
 - South Carolina prohibits using CBD in animal feed, and notified industry on January 3, 2020 that the State will begin sending enforcement letters to companies manufacturing or marketing CBD in animal feed in the state

State-Level Enforcement

- Typical penalties for violations of state pet food regulations:
 - Warning Letter
 - Issuance of Stop-Sale, Hold, or Stop-Use Order
 - Seizure
 - Registration revocation or suspension
 - Civil fines
 - Criminal penalties



Class Action Risks

- Separate from FDA and FTC, CBD-containing animal products are also at risk of challenge by private plaintiffs
- *Fausett v. Koi CBD, LLC* (C.D. Cal., complaint filed Dec. 5, 2019, voluntarily dismissed on Feb. 10, 2020)
 - Sought class action certification under California consumer protection law regarding the use of CBD in pet treats
 - Argued that CBD cannot lawfully be sold in pet ‘dietary supplement’
- *DaSilva v. Infinite Product Company, LLC* (C.D. Cal., complaint filed Nov. 27, 2019)
 - Seeks class action certification under California consumer protection law regarding the use of CBD in pet treats; case is ongoing as of April 10, 2020
 - The suits allege that products made by both Charlotte’s Web and Infinite run afoul of FDA regulations and, consequently, violate California Unfair Competition Law

Competitor Challenge Risks

- Possible that challengers may bring cases before the National Advertising Division (“NAD”) regarding CBD-containing animal products
 - Voluntary self-regulatory body
 - Reviews advertising for truthfulness and accuracy (*i.e.*, **substantiation**)
 - Product performance claims
 - Superiority claims
 - Scientific/technical claims
 - Handles ~150 cases per year; cheaper than traditional litigation
- While there have not been any recent challenges against CBD-containing animal products, NAD has heard a variety of cases on animal drug and feed advertising

Industry Takeaways

- Recent agency withdrawal of animal “supplement” guidance introduces a baseline level of FDA enforcement risk for products marketed as animal “supplements”/animal dosage form products
- CBD industry is growing at a breakneck pace in the US, but poses many regulatory issues, the most important being product safety
 - FDA has not approved or otherwise deemed safe any cannabinoid-containing product marketed for animals
 - Thus, the use of any cannabinoid (including CBD) also presents FDA enforcement risk *and* consumer class action risk
- CBD research is being sought by FDA
 - Industry stakeholders, especially those in the animal food industry, should take an active role in helping FDA develop the best possible scientific bases for issuing new regulations and making product safety findings

Questions?



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