What's the Buzz? The Current State of Regulation of Cannabis, Hemp, and CBD in the FDA World

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FDA Role in Regulation of Cannabis Products

Food Advertising, Labeling, and Litigation Conference

September 27, 2019

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FDA's Policy Interests

- Protecting the public from **harmful products.**
- Protecting the public from **fraudulent products** with **unproven disease claims** (which could result in patients foregoing proven treatments).
- Incentivizing **rigorous scientific research** to support beneficial therapies (through requiring NDAs and NADAS).
- **Protecting human and animal subjects** involved in research (through requiring INDs and INADs).
- Protecting the integrity of the conventional **food supply** and **dietary supplements.**

Regulatory Landscape

- Federal/state **coordination is necessary**:
  - States
  - HHS
  - DOJ/DEA
  - USDA
  - ONDCP
  - Other federal partners

The Agriculture Improvement Act of 2018 (Farm Bill)

- Gives **USDA authority** to issue federal regulations and guidelines concerning hemp production. **Individual States or tribes** desiring primary regulatory authority over hemp production must submit a plan to USDA.
- **Removed hemp from the definition of marijuana** in the Controlled Substances Act (CSA).
  - Hemp: defined as cannabis (*Cannabis sativa L),* and derivatives of cannabis, with extremely low (not more than 0.3 percent on a dry weight basis) concentrations of THC
- **Marijuana is still regulated by DEA** under Schedule 1 of the CSA.

The Farm Bill's Impact on FDA Authorities

- **FDA's authorities** under the FD&C Act and §351 of the PHS Act were **specifically preserved by the Farm Bill**.
- Cannabis and cannabis-derived products are **subject to the same authorities and requirements** as FDA-regulated products **containing any other substance**.

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.
- Regulatory programs and expediting pathways for important **drug development.**
  - Priority Review of NDAs, Fast Track Designation, Breakthrough Therapy Designation

Drug Development from Cannabis

- Development of drugs has focused on using compounds in cannabis: CBD, THC
- **FDA has approved four products for humans**:
  1. Marinol (dronabinol) (1985): nausea from cancer chemotherapy. Schedule III
  2. Cesamet (nabilone) (1985 (2006)): nausea & neuropathic pain. Schedule II
  3. Syndros (dronabinol) (2016): nausea from cancer chemotherapy. Schedule II
  4. Epidiolex (CBD) (2018): for childhood seizures. Schedule V
- **FDA has not approved any products for animals.**

FD&C Act §301(ll): Foods for Humans and Animals

- Under §301(ll)), it is **prohibited** to introduce or deliver for introduction into interstate commerce **any food (including animal food or feed)** to which has been added a substance (such as THC or CBD) which is an **active ingredient in a drug product that has been approved** under FD&C Act §505, or a drug for which **substantial clinical investigations have been instituted** and for which the existence of such investigations has been **made public**.

FD&C Act §301(ll): Foods for Humans and Animals

- Exceptions to §301(ll):
  - If article was **marketed in food before the drug was approved** or **before the substantial clinical investigations** involving the drug had been authorized.
    - *Note: FDA has examined the available evidence and concluded that this exception does not apply.*
  - FDA can also create an exception to §301(ll) through **notice and comment rulemaking**.
- All foods are subject to a number **of other regulatory requirements** related to topics such as: safety of ingredients, production controls, labeling.

Hemp Seed-Derived Ingredients for Human Foods

- FDA completed the evaluation of **three GRAS notices** related to the use of hemp seed-derived food ingredients for human foods in December 2018.
- FDA had no questions about the submitter's conclusion that **the ingredients were GRAS** for the uses in the notice.
- These **products can be legally marketed** in human foods for these uses without food additive approval, provided they **comply with all other requirements and do not make disease claims**.

Food Additives in Animal Food

- All ingredients in animal food must be **approved food additives or GRAS** for their intended use in the intended species.
- At this time, there are **no approved food additives** for any substances derived from hemp and we are **unaware of any GRAS conclusions** for animal food.

FD&C Act §201(ff)(3)(B): Dietary Supplements

- Under §§201(ff)(3)(B)(i) and (ii), if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under §505, or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then **products containing that substance are outside the definition of a dietary supplement**.
- CBD and THC products are therefore **excluded from the definition of dietary supplement** under the FD&C Act regardless of whether the substances are hemp-derived.

FD&C Act §201(ff)(3)(B) Dietary Supplements

- **Exceptions:**
  - If the substance was marketed as a dietary supplement or as a conventional food **before the drug was approved or before the new drug investigations were authorized**, as applicable.
    - *Note: FDA has examined the available evidence and concluded that this exception does not apply.*
  - FDA can also create an exception to §201(ff)(3)(B) through **notice and comment rulemaking**.

Products Marketed as “Supplements” for Pets

- **No category of “dietary supplements” for animals** in FD&C Act. DSHEA does not apply.
  - Many products **(including CBD)** are **marketed as “supplements” for pets.**
- Products marketed as “supplements” for pets may be considered animal food or drugs depending on the intended use.
- CVM’s position is **CBD is inappropriate for use as a “supplement”** for pets as there is a lack of safety data and CBD is not allowed in animal food.

Cosmetics

- **No premarket approval** required for cosmetic products and ingredients, with the exception of color additives.
- Must not be **adulterated.**
  - Safe for consumers when used according to the directions in labeling and under customary/usual conditions of use.
- Must not be **misbranded.**
- **Topical products**, including those that contain **CBD**, intended to affect the structure or any function of the body, or to be used in the diagnosis, cure, mitigation, treatment, or prevention **of disease**, **are drugs**, even if they are also cosmetics (dual classification is common).
  - New drugs must be approved.

Current FDA Warning Letters Related to CBD Products

- FDA issued **numerous WLs** from 2015 to present, including after passage of the Farm Bill:
  - Unapproved new drugs [§§201(p), 301(d), and 505(a)]
  - Misbranded drugs [§§301(a) and 502(f)(1)]
  - Illegally marketed food [§301(ll)]
  - Illegally marketed supplements [§201(ff)(3)(B)]
  - Unapproved new animal drugs [§§301(a) and 501(a)(5)]

- FDA **posted lab results** for dozens of CBD products cited in the warning letters.
  - In many cases, the CBD content did not match the labeled claims and some products did not contain any CBD.

FDA Internal Agency
Marijuana and CBD Working Groups

Marijuana Working Group

- **Focused on** products containing cannabis or cannabis-derived compounds **in general**.
- **Surveillance, enforcement, and policy options** for products containing cannabis or cannabis-derived compounds.

CBD Working Group

- Explore **potential pathways** for dietary supplements, conventional foods, veterinary products, and cosmetics containing **CBD** to be lawfully marketed.
- Consider what the impact of such marketing would be on the **public health**.
- **Consider whether statutory or regulatory changes** might be needed.

FDA Cannabis and Cannabis-Derived Products Q&A Website

https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm

May 31st Public Hearing

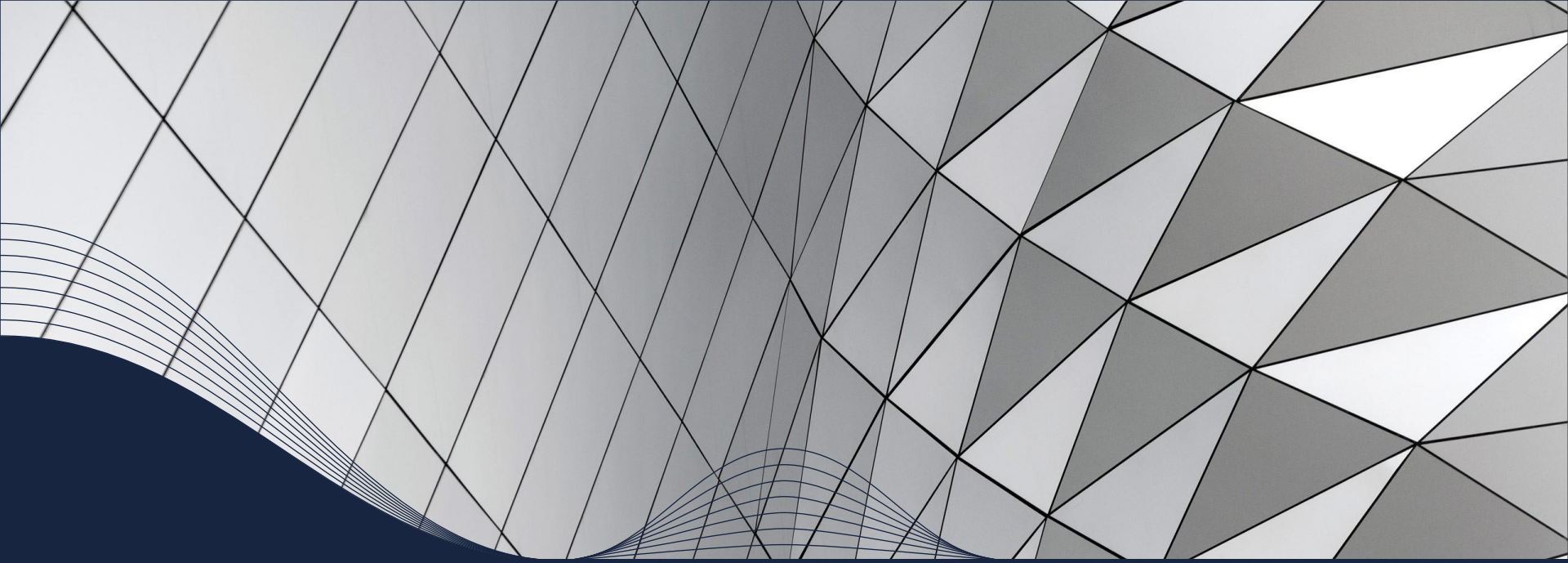
- FDA held a public hearing on May 31, 2019 which provided an opportunity for the agency to obtain additional **scientific data and other information** related to cannabis and cannabis-derived compounds, both from botanical and synthetic sources, **to inform our regulatory oversight of these products**.
  - More than 100 stakeholders presented.
- FDA received 4,492 submissions to the public docket, which closed on July 16, 2019.
- **Specific topics of interest included:**
  - Health and Safety Risks
  - Manufacturing and Product Quality
  - Marketing/Labeling/Sales

Challenges

- Rapidly **changing legal frameworks** at all levels (federal, state, local).
  - Congress may seek to legislate again in the near term.
- Continually **evolving market** with many types of products.
- **Significant missing data** to inform policy regarding use in consumer products, including data related to:
  - Safety,
  - Use by special populations (e.g., pregnant/nursing women, children, adolescents)
  - Cumulative exposure/appropriateness of safe threshold levels
  - Effectiveness of labeling
- Need to support **rigorous scientific research** including potential therapeutic uses and other potential health benefits.

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 more efficient.
- 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.



CBD State Laws

DLA PIPER

CBD State Law Implications – Questions to be Answered

- What's the line between industrial hemp v. hemp product?
- Which state agency is best suited to regulate hemp products?
- What activities are regulated at the state level?
- What happens when FDA releases regulatory framework?

CBD State Law Trends

- **Patchwork of state laws, changing constantly**
  - States with CBD Laws tend to permit CBD in foods & supplements
  - State Guidances (in absence of state laws)
    - Typically align with FDA, prohibiting use in foods/supplements
- **Sourcing hemp and processing hemp out of state**
  - Maine (only allows hemp consumables produced in state) v. NJ (allows hemp products processed out of state)
- **Unique state restrictions**
  - Vermont: prohibits use in meat, milk, and dairy products
- **CBD in Vapes**
  - Washington: prohibits CBD in vapes
  - Massachusetts ban on all vapes

CBD State Law Comparisons

STATE	Laws and Regs Specific to Hemp CBD Consumables?	Is Hemp CBD allowed in foods?	Is Hemp CBD allowed in dietary supplements?	Is Hemp allowed in pet foods?	Any Labeling Requirements?
NY	No (pending bill)	No (per guidance)	Yes (limited)	Unclear	Yes (for supplements)
CA	No (pending bill)	No (per guidance)	No (per guidance)	No (per guidance)	No (pending bill)
FL	Yes	Yes	Yes	Yes	Yes
MA	No (pending bill)	No (per guidance)	No (per guidance)	No (per guidance)	No
TN	No	Yes (per guidance)	Yes (per guidance(	Unclear	No
WA	Yes	Yes	Yes	Yes	No

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