FDA
Regulated Cannabis
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A perfect storm is an event in which a rare combination of circumstances drastically intensifies the event.

Cannabis sativa L.
- Evolving state laws
- Approved prescription drug
- Federally legal hemp (2018 Farm Bill)
- Research burdens down
- Research funding up
- Third party risk going down
- Canada
- Overall Zeitgeist shift
Cannabis sativa L.

**BEFORE 2018 FARM BILL**

**Cannabis sativa L.**

**EXEMPT PARTS**
- Sterile seeds
- Stalks (No Cannabinoids)

**LEGAL HEMP FOOD PRODUCTS**
- Hemp Seed Oil
- Hemp Protein
- Hemp Flour

**AFTER 2018 FARM BILL**

**Cannabis sativa L.**

**HEMP**
- Agricultural Commodity
- Constituents include
  - CBD
  - No THC
  - Other Cannabinoids

**MARIJUANA**
- Controlled Substance
- Constituents include
  - THC
  - CBD
  - Other Cannabinoids

Note: Before the 2018 Farm Bill, hemp was illegal. After the 2018 Farm Bill, hemp became legal for agricultural purposes, with a limit of 0.3% THC.
• **Cannabis sativa** L.
  • Hemp (< 0.3% THC)
  • Marijuana (everything else)

• Cannabinoids
  • CBD
  • THC
  • others

• Terpenes – fragrant volatile compounds providing aromatic flavor profile

• Hemp seed products
  • Hemp seed oil, flour, protein
    • fatty acids and protein
    • cannabinoids absent

• Hemp extracts (hemp oil, CBD oil, full-, broad-spectrum)
  • Each extraction method results in unique profile of bioactive compounds

• Highly purified and isolated CBD
HEMP Agricultural Commodity
- 0.3% THC
- USDA regulations

Legal Hemp Products

Hemp Food/Supplement/Cosmetic

MARIJUANA Controlled Substance

Prescription Drugs

State-Based Recreational And Medical Industries

Cannabis sativa L.

FDA

May 31, 2019
“and so this men of Indostan
Disputed loud and long,
Each in his own opinion
Exceeding stiff and strong,
Though each was partly in the right
And all were in the wrong!”
FDA regulation allows a naturally derived ingredient to co-exist as conventional food, dietary supplement, and drug
✓ Intended use dictates safety, manufacturing standards, and marketing claims
Dietary Supplement

- **Hemp (<0.3% THC)**
  - Hemp Seed Oil
  - Hemp Seed Protein/Flour

- **Botanical Dietary Ingredient**
  - Hemp Extract
    - ETOH
    - CO2
    - Other Method

- **Hemp Extract**
  - CBD/CBDA
  - CBD Concentrated
  - CBD Standardized
  - CBD Highly Purified
  - CBD Isolate

- **All hemp extracts are NDIs**
  *products that were previously in the food supply legally did not contain meaningful amounts of cannabinoids because they were from seed or stalk

- **Each finished dietary ingredient is unique**
  - Safety data
  - Legal/regulatory considerations
  - NDI notification

*CBD synthetic or other source = different regulatory considerations

FDA IND exclusion policy will distinguish supplement ingredients from drug ingredients
Conventional Food

Hemp (<0.3% THC) → Food Additive → Hulled Hemp Seed, Hemp Seed Protein Powder, and Hemp Seed Oil → GRAS notified

Hemp Extract
- ETOH
- CO2
- Other Method

Each ingredient is unique
- Safety data
- Legal/regulatory considerations
- GRAS notified/self-affirmed

FDA IND exclusion policy will distinguish food additive ingredients from drug ingredients. FDA may have additional limitations to ingredients allowed in the food supply as compared to supplements.

Safety considerations with FDA food regulations
- No ingredient ID testing
- No ingredient specifications
- No potency testing
- No age-restricted foods
- No adverse event reporting requirements
- Matrix issues
FDA regulation allows a cannabis derived ingredient to co-exist as conventional food, dietary supplement, and drug

✓ Intended use dictates safety, manufacturing standards, and marketing claims

<table>
<thead>
<tr>
<th></th>
<th>CONVENTIONAL FOOD</th>
<th>DIETARY SUPPLEMENT</th>
<th>PRESCRITION DRUG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw material source</td>
<td>Hemp</td>
<td>Hemp</td>
<td>Marijuana and Hemp</td>
</tr>
<tr>
<td>FDA Ingredient reg/safety standard</td>
<td>GRAS</td>
<td>NDIN</td>
<td>FDA pre-market approval</td>
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<tr>
<td>Claims</td>
<td>taste, aroma, nutritive value</td>
<td>Structure/function claims</td>
<td>FDA approved therapeutic claims</td>
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<tr>
<td>Scope of allowed cannabis ingredients</td>
<td>hulled hemp seed, hemp seed protein powder, and hemp seed oil</td>
<td>hemp extracts, hulled hemp seed, hemp seed protein powder, and hemp seed oil</td>
<td>No limits</td>
</tr>
</tbody>
</table>
The Future

THREE DISTINCT CANNABIS PRODUCT CATEGORIES

1. FDA regulated prescription drugs
   - Epidiolex and more

2. FDA regulated hemp products
   - **Food** - hulled hemp seed, hemp seed protein powder, and hemp seed oil – isolated CBD?, hemp extracts?
   - **Dietary Supplements** – USDA registered food fiber hemp extracts with NDINs – isolated CBD?
   - **Cosmetics** – FDA compliant ingredients meeting cosmetic safety standard

3. State regulated recreational marijuana
   - Full range of THC/CBD products, outside of FDA jurisdiction
   - Limited to intra-state commerce
Thank You!
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