FDA's Cannabis Derived Product Data Acceleration Plan (DAP)

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FDA's Quest for Data

- Since the passage of the 2018 Farm Bill FDA has continually worked to gather information on cannabis derived products (CDPs)
- Safety Concerns
- Testing and Sampling

Data Acceleration Plan (DAP)

- In October 2021 FDA announced the DAP
- Ongoing efforts in the absence of regulatory action
- The plan has four main areas of focus, all of which support the overarching goal of creating data driven process for safety signal detection

1. Evaluating Current Data Sources

- Public docket opened in the spring of 2019
- Goal to use additional online data to:
  - monitor and evaluate the digital marketplace
  - understand usage motivations and patterns
  - understand safety misinformation and the impact on consumer behavior, and
  - inform future research and education opportunities.

2. Cultivation of Collaborative Partnerships

- Establish partnerships to obtain additional data and to learn from diversified experiences
- Interested in partnerships with other government entities (international and domestic) as well as states and stat- based organizations.

3. Accelerating Research

- Research to inform consumer safety
- Focus on Toxicology
- Specific focus on transdermal penetration and pharmacokinetics of CBD and how CDPs affect
  - The male reproductive system
  - Neurological development
  - The risk of liver injury (based on consumption)

4. Plotting CDP Data

- Do these efforts effectively capture data?
- Can they detect safety signals?
- Does data generate other information on potential risks associated with CDPs?
- Pilot project to analyze COAs

Moving Forward

- How will FDA use this information and how will this information impact
  - Regulatory decision making
  - Enforcement actions
  - Additional research

Search for Data: FDA-Regulated (Edible) Cannabis-Derived Products

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FDA-Regulated (Edible) Cannabis-Derived Products

- Edibles
  - “Conventional Food”
  - Dietary Supplements
  - Medical Food

- Claims / Promotion / Marketing
  - Nutrient Content Claim
  - Qualified Health Claim
  - Authorized Health Claim
  - S/F Claim
  - Drug / Disease Claim

FDA-Regulated (Edible) Cannabis-Derived Products

- 301(ll) / 201(ff)(3)(B)(ii) and the Identity of the “Article of Commerce”
  - Isolate
  - Broad Spectrum
  - Full Spectrum

- Regulatory Pathways to Market
  - Food Additive Petition
  - Generally Recognized as Safe Notification
  - Self-GRAS Determination
  - New Dietary Ingredient Notification

- “Data to inform”