



Association of Western Hemp Professionals

RE: Hemp Cultivation Tracking Initiatives

The current status of hemp-derived cannabinoid is rife with uncertainty but plenty of potential. As of 2020, while many states have clear legal pathways to hemp-derived cannabinoid products, the FDA has been resolute in their determination that due to new drug implications from the introduction of Epidiolex, hemp-derived CBD is not an approved dietary/food ingredient. In order to make the case that hemp-derived CBD is an appropriate ingredient for the food supply, industry must do its part to submit production and safety data to inform its qualification as such.

In an effort to inform FDA and state legislators on their decisions for potential future changes to be reflected in a final rule for hemp-derived cannabinoid products, it is prudent for our members involved in processing, product manufacturing and product marketing to track key metrics during the 2020 season:

**Anonymity respected*

- 1. Processes used for extraction, distillation, isolation, etc.*
- 2. Product types manufactured*
- 3. Analytical procedures*
 - a. Internal testing methods*
 - b. Third-party testing methods*

4. *Clinical Studies (if applicable) [taken from FDA current docket request¹]*
 - a. *For isolated CBD and full/broad-spectrum hemp extracts*
 - b. *Safety/ Tolerability research*
 - i. *Especially acute and long-term outcomes related to male reproductive toxicity and liver toxicity*
 - c. *Driving impairment research*
 - d. *Alcohol interaction research*
 - e. *Dermal penetration research*
5. *Safety data surveillance/studies (for isolated CBD and full/broad-spectrum hemp-extract)*
 - a. *Chronic exposure data*
 - b. *Vulnerable population data*
6. *Adverse event data*

¹ <https://www.fda.gov/news-events/public-health-focus/information-cbd-data-collection-and-submission>