Cannabinoid Manufacturing: Product Quality & Safety

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Established FDA Commitment to Quality and Safety for Cannabinoid Products

- FDA has previously approved drugs containing CBD and THC, thereby ensuring comprehensive oversight of the products
- 2018 Farm Bill explicitly preserved FDA's authority to regulate CBD products in furtherance of the agency's mandate to protect public health
- All cannabinoid products should be held to the same rigorous, quality, safety, and efficacy standards established by FDA to protect the public

Current Landscape

- Marked by (1) proliferation of cannabinoid containing products and (2) confusion about the legality of distribution and differences between federal and state regulatory oversight of cannabis and cannabinoids

- Established Risks with non-FDA Regulated Cannabis:
  - Lab analyses demonstrate that some non-FDA approved but commercially available CBD products do not contain what is listed on their product labels[1]
    - FDA's independent lab testing has shown similar results
    - In addition, CBD product testing has shown the presence of THC at levels which may be sufficient to produce a negative euphoric effect, particularly among children
  - Common cannabis contaminants include microbes (bacteria and fungi), heavy metals and pesticides[2]
    - Microbial contamination may occur during improper preparation and storage of cannabis products and can result in infections
    - Heavy metal contaminates may be attributable to soil, fertilizer and/or cross-contamination during processing
    - Pesticide use in the cultivation of cannabis crops is well established

[1] Vandrey R, Raber JC, Raber ME, Douglass B, Miller C, Bonn-Miller MO. Cannabinoid dose and label accuracy in edible medical cannabis products. JAMA. 2015;313(24):2491-2493.
Bonn-Miller MO, Loflin MJE, Thomas BF, Marcu JP, Hyke T, Vandrey R. Labeling accuracy of cannabidiol extracts sold online. JAMA. 2017;318(17):1708-1709.
[2] Grof CPL, Galettis P, Martin JH, Dryburgh LM, Bolan NS, Schneider J, and Lucas CJ. Cannabis contaminants: sources, distribution, human toxicity and pharmacologic effects. British Journal of Clinical Pharmacology. 2018;84,(11):,2468–2476.

FDA should continue to enforce pharmaceutical compliant cGMP processes & testing standards to ensure product quality and safety for all commercially distributed cannabinoid products

- Pharmaceutical product development, evaluation & processes are well-defined in FDA & international guidance documents
- Testing limits & controls for each stage of product development are established
- Existing pharmaceutical development, manufacturing & quality assurance processes ensure product quality, label accuracy & minimize the risk to public safety

FDA should continue to leverage the existing robust regulatory framework in the oversight of cannabinoids

Product Quality Manufacturing Controls Ensure Product Identity, Purity, Strength, Quality and Label Accuracy

- Control of raw materials, solvents, impurities, herbicides, pesticides & fungicides
- Documented manufacturing processes & in-process testing
- Microbial testing to ensure acceptable levels are not exceeded
- Controlled storage conditions to safeguard against the impact of moisture, light, packaging & oxygen exposure
- Product stability and shelf life testing

Summary

- FDA has a well-established history of protecting the public health
- Existing regulations & processes governing the manufacture of pharmaceutical products establish critical controls to ensure necessary quality & safety standards are met
- This robust framework can & should be leveraged in the regulation of all cannabinoid products
- Less stringent manufacturing & quality standards would create an unnecessary public health risk