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 labels¹
    • 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 pesticides²
    • 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

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.

- FDA regulatory oversight, guidance, review and inspection
- Good Manufacturing Procedures (cGMP) Regulations
- International Conference on Harmonization (ICH) Guidelines
- US Pharmacopeia (USP) & National Formulary (NF) Standards
- Drug Product Track and Trace Requirements
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