CV SCIENCES FDA CBD HEARING PRESENTATION TRANSCRIPT
May 31, 2019

(Title Slide)
My name is Douglas MacKay, Senior Vice President, Scientific and Regulatory Affairs for CV Sciences. CV Sciences operates two distinct divisions.

The consumer division delivers hemp products through its PlusCBD™ Oil brand, the pharmaceutical division is pursuing an FDA approved drug.

Responsible industry embraces robust FDA regulation. An appropriate and predictable regulatory framework protects consumers, while allowing a pathway for companies to lawfully market various types of cannabis-derived products.

Industry appreciates the challenging task of striking the right balance between consumer access and consumer safety.

We applaud FDA for the significant work done so far to respond to the rapidly changing environment.

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USDA and FDA have been tasked with developing regulations that separate an Agricultural Commodity from a Controlled Substance.

Let me repeat that:
Separating and *Agricultural Commodity* from a *Controlled Substance*

Responsible industry strongly encourages that FDA and USDA closely collaborate to ensure that corresponding regulations are synchronized to efficiently differentiate the hemp and marijuana supply chains.

(Slide 3)
International hemp regulatory models apply a seed licensing and registration scheme that ensures that only appropriate food-fiber hemp cultivars are used as a raw material source for hemp-based industries.

(Slide 4)
A verified food/fiber hemp supply chain provides a safe, non-intoxicating botanical starting material. Hemp - can be safely regulated by FDA like other natural ingredients.

Current FDA regulation allows a naturally derived ingredient to co-exist as conventional food, dietary supplement, and drug.

This slide provides examples of different ingredients, derived from the same natural resource, being appropriately marketed in different lanes.

CV Sciences suggests that new FDA rule-making is not required if FDA provides clear Industry Guidance to the type and scope of hemp ingredients allowed in each FDA regulated category.

(Slide 5)
For conventional food products – FDA has completed 3 GRAS notices for hemps seed-derived food ingredients. The food pathway is clear for companies that want use the nutrient-rich components of hemp in food or develop new ingredients.

(Slide 6)
The drug regulatory pathway is also clear for companies that want to develop new drugs and botanical drugs to treat disease.

(Slide 7)
For supplements FDA has been clear that highly purified and isolated CBD can't be added to food or dietary supplements. However, scientific and legal experts agree that a hemp extract containing a full array of cannabinoids, and other plant constituents is a significantly different 'article' than a highly purified CBD - Each has a unique identity and unique biological activity.

CV Sciences suggests that FDA guidance that differentiates a hemp extract from a prescription CBD would allow companies to confidently file the requisite NDI Notifications.

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Today, FDA has made a broad request for data on cannabis safety. To satisfy this request one must first qualify the specific composition of the cannabis-derived ingredient and second the intended use of the ingredient.

Cannabis or hemp product safety is based on the chemistry of the ingredient and the intended use.

FDA regulations, when evaluated holistically, provide an appropriate framework to regulate cannabis for different intended uses.

A product intended to treat children with epilepsy is a drug and should come with the pre- and post-market rigor of FDA approved drugs.

However, a food product that provides nutrition or a supplement that supports a healthy lifestyle have regulatory paradigms that appropriately correspond with those uses.

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CV Sciences looks forward to submitting detailed written comments to share our experience working with hemp. Time constraints will only allow me to share a few ways that we ensure that we provide consumers with safe and high-quality hemp products.

- We start with food/fiber hemp cultivars from licensed and registered hemp seeds
- We establish the identity of our ingredient through chemical analysis
- We publish the appropriate toxicology studies on our ingredient
- We manufacture in a 3rd party GMP verified facility
- And we are compliant with labeling and marketing regulations, as well as Adverse Event Reporting requirements

In closing, I want to emphasize that responsible hemp companies and FDA have a shared goal of protecting consumers while providing access to appropriate hemp products.

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Thank you for this opportunity to share our experiences and we look forward to providing more substantive written comments.

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