

PRODUCTS CONTAINING CANNABIS OR CANNABIS-DERIVED COMPOUNDS

Presented by

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TAKEAWAYS

- Need for interim FDA guidance to encourage thoughtful and sensible regulations
- 2. Need for federal guidance to reconcile varying state laws/regulations and create baseline standard
- 3. Existing FDA standards GMP regulations, labeling, warnings/disclaimers, testing and more provide an existing framework to ensure safety and regulate hemp products
 - 1. No need to re-invent wheel hemp is an agricultural commodity
- 4. Further research is needed to contribute to developing protective standards

MARKETING/LABELING/SALES

- FDA maintains existing product label regulations and standards applicable here
- Sufficient opportunity to inform consumers of associated risks
 - Use of existing and newly developed disclaimers, conventional warnings and directions for use
- Little need, identified to date, to specially regulate use by vulnerable human populations
- As with other industries, relies on manufacturers to comply and disseminate information to consumers
- Need for reconciliation amongst varying state laws and regulations as opposed to special hemp laws separate and apart from food regulations

MANUFACTURING AND PRODUCT QUALITY AND SAFETY

- Existing GMP regulations are workable other agricultural commodities and products utilize solvents and are intended for ingestion/consumption
- Able to be enforced by state and local authorities consistent with other food additives/dietary ingredients
- Testing for potency, contaminants (heavy metals, pesticides, etc.) is currently available
 - Including from well-reputed testing companies with decades of experiences and pedigree in food additives
- Terminology: Full spectrum hemp [extract/oil]; Broad spectrum hemp [extract/oil]; [Cannabidiol or another cannabinoid] isolate, and Hempseed oil.

HEALTH AND SAFETY

- Hemp-derived cannabinoids such as CBD contain a "good safety profile;"
- But, federal laws have stifled sensible research into cannabis-derived compounds
- Need for federal guidance to encourage additional clinical and other research by universities and other conventional research resources
- Need to sensibly distinguish drug development from other existing, conventional and more accessible product types

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