



FDA Public Hearing Cannabis Derived Compounds May 31st 2019

Hemp Derived Products Are Manufactured to High Standards Today



High Mfg. & Product Quality Standards...

Current State

Future State

Consumer Safety

- Setting applicable manufacturing standards of CBD raw materials (e.g., low levels of psychoactive compounds such as THC)
- Federal & state regulatory agencies to jointly develop guidelines (e.g., consumer product specifications) with manufacturers

Quality Management Systems

- Production and process control with complete traceability from farm to product (e.g., SOP's, Master Manufacturing Records)
- Need infrastructure to support higher quality control on federal level (e.g., cGMP, FSMA, GFSI, PCQI compliance)

Validated Testing

- Sophisticated lab testing services available to keep manufacturing in compliance with state regulations (e.g., pesticides, microbials, etc.)
- Standardized testing methods developed by federal agencies (e.g., NIST, USDA) & industry to be adopted by stakeholders

...Build A Stronger Consumer Safety Infrastructure

 Quality Transparency: Inform end-consumers through regulations on packaging & labeling (e.g., warnings and disclaimers for THC content, cannabinoid purity)

| Supplement Facts Serving Size: One Tablet | | |
|---|---------|---------------|
| One Tablet Contains: | | %DV |
| Vitamin A (50% as retinyl acetate and | | |
| 50% as beta-carotene) | 5000 IU | 100% |
| Vitamin C (as ascorbyl palmitate) | 15 mg | 25% |
| Thiamine (as Thiamine mononitrate) | 12 mg | 800% |
| Niacin (as niacinamide) | 60 mg | 300% |
| Copper (as cupric oxide) | 1 mg | 50% |
| Potassium (as potassium chloride) | 10 mg | <1% |
| Boron (as aspartate) | 200 mcg | $\overline{}$ |
| Tyrosine (as L-Tyrosine) | 100 mg | • |
| Taurine | 100 mg | |
| Licorice (root) Glycyrrhiza glabra | 50 mg | • |
| Milk Thistle extract (seed) Silybum | | • |
| Marianum (80% Silymarin) | 50 mg | • |
| * Daily Value (DV) not established | | |

| 8 servings per container Serving size 2/3 cup (55 | | |
|--|--------|--|
| Amount per serving Calories 2 | 3 | |
| % Dail | y Valu | |
| Total Fat 8g | 10 | |
| Saturated Fat 1g | 5 | |
| Trans Fat 0g | | |
| Cholesterol Omg | 0 | |
| Sodium 160mg | 7 | |
| Total Carbohydrate 37g | 13 | |
| Dietary Fiber 4g | 14 | |
| Total Sugars 12g | | |
| Includes 10g Added Sugars | 20 | |
| Protein 3g | | |
| Vitamin D 2mcg | 10 | |
| Calcium 260mg | 20 | |
| Iron 8mg | 45 | |
| Potassium 235mg | - | |

- Ingredient Safety: Create pathway for NDI & GRAS notifications for hemp derived extracts as a dietary ingredient & food additive (e.g., similar to fish oils)
- Product Safety: Providing consumer assurance through federally validated quality management systems and manufacturing compliance standards to create products with ingredients consumers can trust (e.g., USP monograph)

And tomorrow, federal regulations allow manufacturers to serve consumers with higher quality & safety standards