Standards for Hemp

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Hemp: Definition and Regulatory Status

- The plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

- FDA has completed the evaluation of three Generally Recognized as Safe (GRAS) notices for hemp ingredients.

- “No questions” letters issued in response to GRAS notices for:
  - hulled hemp seed (GRN765)
  - hemp seed protein powder (GRN771)
  - hemp seed oil (GRN778)
Dietary Supplement Admission Evaluation Process

Selection of a Dietary Ingredient for Monograph Development

Collection of Safety Information

Evaluation of Information by EC

Class A

Class B

No Monograph

Monograph Development by DS EC

Adverse Report

Apparent Efficacy

Demand

Public Protection

Human Data

Pharmacological Data

Contemporaneous Extent of Use

Compendial Presence

Feasibility

Safety

Historical Use

Regulatory Status

Official Monographs

Major Considerations

1. Fingerprint based on cannabinoid profile (characteristic ID for hemp)
2. Limit for $\delta_9$-THC (NMT 0.3% on a dry weight basis, inclusive of THCA)
3. Test for CBD – minimum content or % of label claim contingent with the FDA decisions or Congressional actions about levels allowed in non-drug products
4. Specific Tests for terpene profile
5. Limits for containments:
   - Pesticide residues (<561>)
   - Microbial load (<2022> and <2023>)
   - Elemental contaminants (<561> and <2232>)
   - Residual solvents (<467>)

USP receptive to scientific dialogue, additional information on the need for quality standards, and data/specifications to support admission evaluation
Thank You

Empowering a healthy tomorrow