Hemp Ingredients
Dietary Supplements
Conventional Food

PRESENTED BY
Douglas MacKay, SVP of Scientific and Regulatory Affairs
CVSI
FDA Public Meeting
May 31, 2019
HEMP AND MARIJUANA COMPARED,  
0.3% THC IS ONLY ONE small DIFFERENCE

Agricultural Commodity  
vs.  
Controlled Substance
“For the support you can only use the Cannabis types....listed in the common seed catalog and published according to article 17 of the guideline”

“Cannabis seed types which are not allowed in Germany 2017”
- Hot Crops
FDA regulation allows a naturally derived ingredient to co-exist as conventional food, dietary supplement, and drug

- Intended use dictates safety, manufacturing standards, and marketing claims
Hemp seed derived products can be legally marketed in human foods, provided they comply with other FD&C requirements.

FDA completed three generally recognized as safe (GRAS) notices for hemp seed-derived food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil.

FDA had no questions regarding the safe use of these ingredients in humans.
There is active research exploring new cannabis-derived and cannabis-related drugs.

FDA has approved one cannabis-derived and three cannabis-related drug products. These approved products are only available with a prescription from a licensed healthcare provider.

DISTINCT REGULATED PRODUCT CATEGORIES – food, supplements, drugs
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1. Dietary Supplement – Guidance for industry needed on the scope of allowed hemp-derived dietary ingredients (purity, potency, and composition)

2. New Dietary Ingredient Notification (NDIN)
   1) Describe ‘identity’ of ingredient (a.k.a., ‘the article’)
   2) Provide evidence of safety for the described ingredient for the intended use

3. Other FD&C requirements for dietary supplements
   • cGMP
   • Labeling and claims
   • Adverse Event Report (AER) record keeping and recording requirements
<table>
<thead>
<tr>
<th></th>
<th>CONVENTIONAL FOOD</th>
<th>DIETARY SUPPLEMENT</th>
<th>PRESCRITION DRUG</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Source</strong></td>
<td>Hemp</td>
<td>Hemp</td>
<td>Marijuana, Hemp, and Synthetic</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>GRAS</td>
<td>NDIN</td>
<td>pre-market approval</td>
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<tr>
<td><strong>Claims</strong></td>
<td>taste, aroma, nutritive value, or technical effect</td>
<td>structure/function</td>
<td>therapeutic (pre-approved)</td>
</tr>
<tr>
<td><strong>Scope of allowed cannabis ingredients</strong></td>
<td>hulled hemp seed, hemp seed protein powder, and hemp seed oil</td>
<td>hemp extracts + (hulled hemp seed, hemp seed protein powder, and hemp seed oil)</td>
<td>No limits</td>
</tr>
</tbody>
</table>
Responsible Industry Pillars

- Starting material – food/fiber hemp cultivars from licensed and registered hemp seeds
- Ingredient identity – supplement/food ‘article’ is different composition than drug ‘article’
- Ingredient meets FDA safety standards
- 3rd party cGMP verified manufacturing
- FDA compliant labeling and claims
- Post Market Surveillance (AER record keeping and reporting)
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Audit Recognition

This acknowledges that
CV Sciences
10070 Barnes Canyon Rd
San Diego, California, 92121

has successfully completed
Eurofins Dietary Supplement Audit

Credible Results. Incredible Service."
Thank You!

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