SafeFoodTeam

Manufacturing of Hemp Products

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Outline of the Presentation

- Review some terms
- Discuss the 2018 Farm Bill
- Discuss the current position of the Food and Drug Administration
- Review specific regulations for food manufacturers and manufacturers of dietary supplement product
- Claims!
- Questions?
    - Acknowledgment: Pictures provided by Kelli Story, Green Queen Candies, Greensboro, VT, and Kria Botanical, South Burlington, VT

Disclaimer!

- You will hear about food safety regulations
  - I work in regulatory compliance
  - But I do not provide legal advice!
- There are always “interpretations” of regulations
- This topic is evolving and still in flux
- Terms are still been defined and re-shaped

Microbial Risk Analysis

ISSN: 2352-3522

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Professor Omar Oyarzabal

The peer-reviewed journal Microbial Risk Analysis accepts articles dealing with the study of risk analysis applied to microbial hazards. Manuscripts should at least cover any of the components of risk assessment (risk characterization, exposure

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Time to First Decision	Review Time	Publication Time
3.8 weeks	7.6 weeks	0.9 weeks

Which One Do I Work with?

Food Processor

Food Processor

Which One Do I Work with?

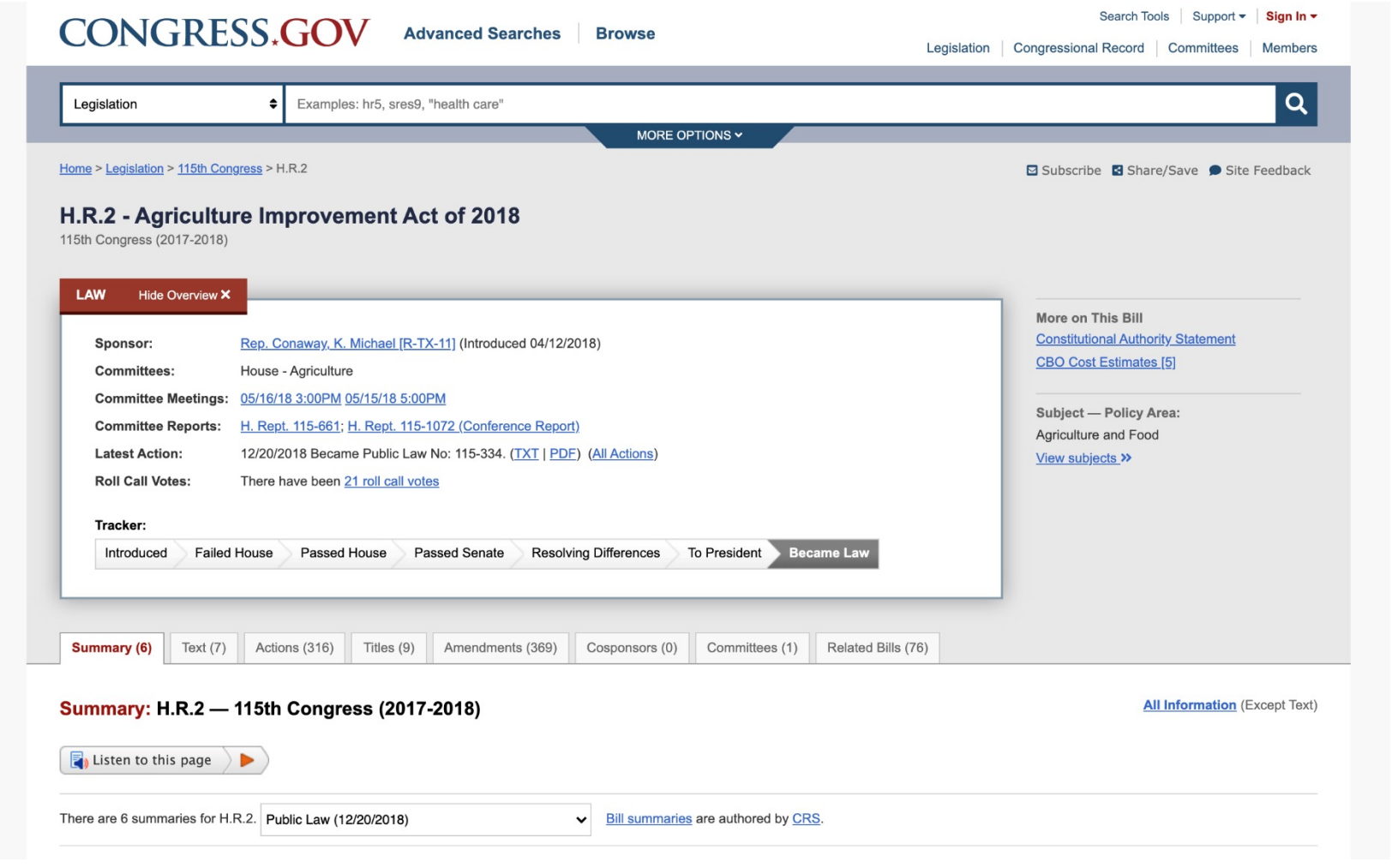
Food Processor

Food MANUFACTURER

Food Safety and Modernization Act
21 CFR § 117.3 Definitions

- **Manufacturing/processing** means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients…
- Examples: Baking, boiling…canning, cooking, cooling, cutting…. distilling…homogenizing… labeling…packaging…trimming… waxing…
- …manufacturing, processing, packing, or holding food
- …manufacturing/processing, packing, or holding food

Agriculture Improvement Act of 2018
(2018 Farm Bill)



2018 Farm Bill

Hemp: Plant *Cannabis sativa* L. and any part of that plant, including:

- Seeds thereof and all derivatives
- Extracts
- Cannabinoids (and isomers)
- Acids
- Salts (and salts of isomers)

"…whether growing or not, with THC (delta-9-tetrahydro-cannabinol) concentration of not more than 0.3% on a dry weight basis"

Cannabis Plants

THC Test Results

(% of THC on a dry weight basis)

Hemp: < 0.3% THC

Cannabis with THC > 0.3% THC

Important Terms

- **Cannabinoids** = Many related compounds (100+) in the plant (e.g., CBD, THC), primarily in the flowering tops and absent in seeds
  - **THC** = A cannabinoid responsible for psychotropic effects
- **Cannabis** = Any part of the plant *Cannabis sativa* L. It includes both hemp and marijuana
  - **Hemp** = Cannabis with THC content less than 0.3%
  - **Marijuana** = Cannabis with THC content above 0.3%

2018 Farm Bill

- Removes restrictions from the jurisdiction of the Drug and Enforcement Agency (Control Substance Act) for all:
  - Growing and cultivation of "industrial hemp"
  - All part of the hemp plant (0.3% THC or less)
  - The Secretary of Agriculture in all states can monitor and control growing and cultivation of hemp plants
    - Uniformity for trade
- The 2018 Farm Bill <u>does not change the way FDA enforces its regulations</u>
- <u>FDA regulates food manufacturers</u>

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  - **Hemp** = Cannabis with THC content less than 0.3%
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- **Cannabidiol (CBD)** = Compounds from the *Cannabis* plant without psychotropic effects
  - **CBD** = Active compound of an FDA-approved epileptic **drug**


100 mL
NDC 70127-100-10
Epidiolex®
(cannabidiol)
100 mg/mL
Oral Solution
For oral administration
Read enclosed instructions before using this product.
Attention Pharmacist: Dispense the enclosed
Medication Guide to each patient
GREENWICH
BIOSCIENCES
Rx Only

FDA NEWS RELEASE

FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy

More Press Announcements

For Immediate Release: June 25, 2018

Español

The U.S. Food and Drug Administration today approved Epidiolex (cannabidiol) [CBD] oral solution for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. This is the first FDA-approved drug that contains a purified drug substance derived from marijuana. It is also the first FDA approval of a drug for the treatment of patients with Dravet syndrome.

CBD is a chemical component of the Cannabis sativa plant, more commonly known as marijuana. However, CBD does not cause intoxication or euphoria (the “high”) that comes from tetrahydrocannabinol (THC).

It is THC (and not CBD) that is the primary psychoactive component of marijuana.

“This approval serves as a reminder that advancing sound development programs that properly evaluate active ingredients contained in marijuana can lead to important medical therapies. And, the FDA is committed to this kind of careful scientific research and drug development,” said FDA Commissioner Scott Gottlieb, M.D. “Controlled clinical trials testing the safety and efficacy of a drug, along with careful review through the FDA’s drug

Content current as of:
03/27/2020

FDA-Approved Drugs Containing CBD or Cannabis-Derived Compounds

- Epidiolex, purified CBD, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome (1 year of age and older)
- Marinol and Syndros, dronabinol (dronabinol and synthetic THC) for the treatment of anorexia in AIDS patients
- Cesamet, nabilone (nabilone, synthetic, similar to THC), for the treatment of nausea and vomiting caused by cancer medications

FDA Position

- Hemp and CBD are not the same
  - CBD is a drug
- No use of CBD as food, dietary ingredient or cosmetic
  - Yet, FDA is using an “enforcement discretion”

FDA NEWS RELEASE

FDA Warns Companies Illegally Selling CBD Products

More Press Announcements

For Immediate Release: December 22, 2020

Today, the U.S. Food and Drug Administration issued five warning letters to companies for selling products containing cannabidiol (CBD) in ways that violate the Federal Food, Drug, and Cosmetic Act (FD&C Act). All five warning letters address the illegal marketing of unapproved CBD products claiming to treat medical conditions. The warning letters include CBD products that are especially concerning from a public health perspective due to the route of administration, including nasal, ophthalmic and inhalation. In addition, they address violations relating to the addition of CBD to food, and the impermissible marketing of CBD products as dietary supplements. Two of the letters also address CBD products illegally marketed for pets, including a product for use in the eye.

"The FDA's first priority is to protect the health and safety of Americans. Many questions remain regarding the science, safety, effectiveness and quality of products containing CBD," said FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D. "We remain focused on exploring potential pathways for CBD products to be lawfully marketed while also educating the public about these outstanding questions of CBD's safety.

Content current as of:
12/22/2020

Regulated Product(s)
Drugs

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5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC

Consumer Updates

- Animal & Veterinary
- Children's Health
- Cosmetics
- Dietary Supplements
- Drugs
- Food
- Medical Devices
- Nutrition
- Radiation-Emitting Products
- Tobacco Products

Español

Content current as of:
09/14/2021

Regulated Product(s)
Animal & Veterinary
Dietary Supplements
Drugs
Food & Beverages

Labels, Claims

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FRIDAY, OCTOBER 6, 2017

NEWS

Jars of CBD-Infused Broth Recalled by Maker

POSTED BY SALLY POLLAK ON FRI, OCT 6, 2017 AT 7:00 AM

A jar of recalled chicken broth | PHOTO COURTESY OF VAAFM

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- USDA inspected product
- CBD added after inspection

FDA Position

- The Food Drug and Cosmetics Act prohibits the "interstate" commerce of any food to which a drug (section 505 of the Act) has been added
- Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition (FD&C Act)

Have the industry tried to get CBD to be considered a dietary supplement by FDA?

- Yes
- Dietary Supplement Health and Education Act (DSHEA), 1994

DSHEA, 1994

- Allows for structure function claims
- Old dietary ingredients (prior to 1994): permitted to be marketed and sold without prior approval by FDA
- New Dietary Ingredients: can be marketed only after pre-market notification
- Could CBD be “grandfathered” as old dietary ingredient?
  - No
- Reasons:
  - GW Pharmaceuticals: Epidiolex (CBD) and Sativex (THC and CBD)
- For FDA there is no evidence that CBD was legally marketed/sold as dietary supplement prior to GW’s clinical investigations

Cannabis Plants

THC Test Results

(% of THC on a dry weight basis)

Hemp: < 0.3% THC

Cannabis with THC > 0.3% THC

Cannabis Plants

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Hemp: < 0.3% THC

Cannabis with THC > 0.3% THC

Marijuana:

- Schedule I controlled substance
  - Illegal under federal law
- Several state permit the sale of marijuana products:
  - Medicinal
  - Recreational use
  - Decriminalized or not

Cannabis Plants

THC Test Results

(% of THC on a dry weight basis)

Hemp: < 0.3% THC

Hemp products:

- **Food ingredients**
  - **GRAS compounds**
- **Dietary supplements**
- **Cosmetics**
- **Drugs**?

Cannabis with THC > 0.3% THC

Marijuana:

- Schedule I co[illegible]ed substance
  - Illegal und[illegible]federal law
- Several state[illegible]erni[illegible]the sale of marijuana[illegible]oducts
  - Medicinal
  - Recreational use
  - Decriminalized or not

Provided by Kria Botanicals, South Burlington, VT

Manufacturing

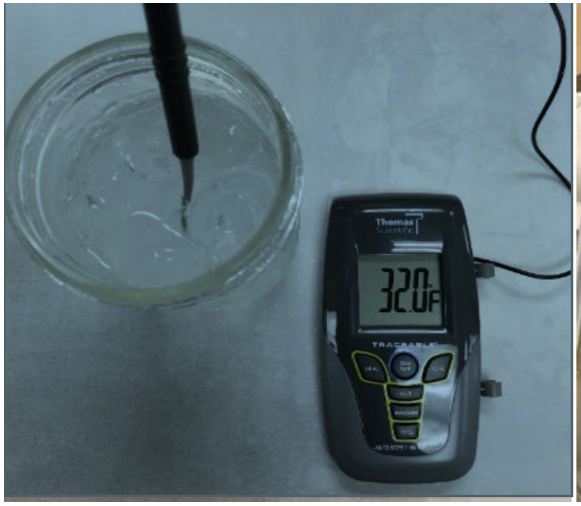
Flowers

Extracts

MCR Labs: https://mcrlabs.com/cannabis-science

Edibles

Provided by Kelli Story, Green Queen Candies, Greensboro, VT


Thomas
320°F
TRACEABLE

General Manufacturing Steps

- Extraction of compounds (cannabinoids)
  - Extract
- Purification of the compound through further or post processing
  - Purified extract
- Further manufacturing
  - Mixing ingredients, making “infusions”
- Packaging and labeling cannabis products

What Can Be Legally Federal Trade Used as Food Ingredient?

- **GRAS Notices from 2018**: Hemp-derived substances for which FDA has no objections when the ingredient is used "under its intended conditions of use" (2018 Farm Bill)
  - Hulled hemp seed (GRN 765)
  - Hemp seed protein powder (GRN 771)
  - Hemp seed oil (GRN 778)

Specific Regulations for Food Manufacturers

- Manufacture foods following Current Good Manufacturing Practice (21 CFR 117, Subpart B)
- Use only approved, safe food ingredients, color and additives (21 CFR 70, 172, etc.)
- Foods are packed in food approved containers (21 CFR 176-186, etc.)
- Food is “honestly” labeled. e.g., Nutrition Facts panel, serving sizes, etc.
- Be consistent with any nutrient claim (21 CFR 101)

CGMPs – Foods

21 CFR Part 117, Subpart B - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foo

- **Subpart B – Current Good Manufacturing Practice**

  §117.10 Personnel

  §117.20 Plant and grounds

  §117.35 Sanitary operations*

  §117.37 Sanitary facilities and controls

  §117.40 Equipment and utensils

  §117.80 Processes and controls*

  §117.93 Warehousing and distribution

  §117.95 Holding and distribution of human food by-products for use as animal food

  §117.110 Defect action levels

  **** Some may be preventive controls (Subpart C)***

Dietary Supplements

- **Dietary supplements**: Products taken by mouth that contain a "dietary ingredient"
- **Dietary ingredients**: Vitamins, minerals, amino acids, herbs or botanicals, and other substances that can be used to supplement the diet
- **Labels**:
  - The label should be "truthful," "honest"
  - Federal laws do not require:
    - Dietary supplements to be proven safe before they are marketed (no pre-market approval)
    - That the manufacturer or seller of dietary supplements prove that claims made in label are accurate

CGMPs – Dietary Supplements

21 CFR Part 111 - Current Good Manufacturing Practice In Manufacturing, Packaging, Labeling, Or Holding Operations For Dietary Supplements

- Subpart A - General Provisions
- Subpart B - Personnel
- Subpart C - Physical plant and grounds
- Subpart D - Equipment and utensils
- Subpart E - Requirement to establish a production and process control system
- **Subpart F - Production and process control system: requirements for quality control**
- Subpart G - Production and process control system: requirements for components, packaging, and labels and for product that you receive for packaging or labeling as a dietary supplement
- Subpart H - Production and process control system: requirements for the master manufacturing record
- **Subpart I - Production and process control system: requirements for the batch production record**
- **Subpart J - Production and process control system: requirements for laboratory operations**
- Subpart K - Production and process control system: requirements for manufacturing operations
- Subpart L - Production and process control system: requirements for packaging and labeling operations
- Subpart M - Holding and distributing
- **Subpart N - Returned dietary supplements**
- **Subpart O - Product complaints**
- Subpart P - Records and recordkeeping

Where Is the industry Going?

- Dietary supplement products
  - Structure function claims
- A lot of testing for potency
  - Still large variation in methodologies
- Drugs
  - More natural and synthetic drugs may be coming to the market

What About States?

- It depends
- How important is the business for the state?
  - $730 millions in California in 2019
- How organized is the industrial hemp program?
- How many resources does the state have to support farmers and manufacturers?
- Are there financial incentives?

Hemp and Cannabidiol (CBD) Products

Hemp and cannabidiol products derived from hemp may be legally sold in Vermont. Hemp plants that are purchased as an agricultural supply are exempt from the Vermont Sales and Use Tax under the agricultural exemption. Cannabidiol is generally subject to the Vermont Sales and Use Tax, with the exception of one form of cannabidiol that has been approved by the FDA, and therefore qualifies for the drug exemption from sales tax. Additionally, cannabidiol that is incorporated into a taxable meal is subject to the Vermont Meals and Rooms Tax and as a result, is exempt from sales tax. The explanation below summarizes the legal basis for taxing or exempting hemp and cannabidiol products in Vermont.

Disclaimer: This information does not constitute legal advice. Vermont tax statutes, regulations, court decisions, or Vermont Department of Taxes rulings supersede information provided here.

Vermont Sales and Use Tax

Vermont imposes a 6% sales and use tax on retail sales of tangible personal property in Vermont, unless an exemption applies. 32 V.S.A. § 9771(1). Tangible personal property is personal property that "may be seen, weighed, measured, felt, touched, or in any other manner perceived by the senses." 32 V.S.A. § 9701(7). Vermont law exempts the sale of certain categories of tangible personal property from tax, including drugs intended for human use, agricultural supplies, food and food ingredients including dietary supplements,

Hemp in food

Environmental Health & Sustainability
Cottage foods
Industrial hemp in food
Manufactured food

The State Health Department's Hemp Program regulates and inspects all hemp manufacturing operations in Colorado. While farms are licensed and regulated by the Colorado Department of Agriculture, once the crop leaves the farm it is this department's responsibility to oversee the manufacturing, packaging, testing and distribution of all hemp products. This includes extraction, any additional processing, and the relabeling of all industrial hemp containing food, supplement, and cosmetic products.

Colorado Revised Statues (C.R.S.) §35-61-101(7) defines industrial hemp as:

"... a plant of the genus cannabis and any part of the plant, whether growing or not, containing a delta-9 tetrahydrocannabinol (THC) concentration of no more than three-tenths of one percent on a dry weight basis."

Colorado

- Dept of Public Health & Environment oversees:
  - Manufacturing, packaging, testing and distribution of all industrial hemp products
  - Food, dietary supplements and cosmetics
- The manufacturer must demonstrate:
  - Be in compliance with the governing laws of the state (licenses)
  - Product comes from approved suppliers (licensed by the Colorado Department of Agriculture) and conform with “standard of identity”
  - The product must be clearly labeled as containing industrial hemp
  - Should include a "not tested by FDA for efficacy and safety"
  - Advertising on packaging or media cannot include any health claims

Official website of the State of California

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Department of Cannabis Control
CALIFORNIA

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Notice: DCC is soliciting proposals for the Local Jurisdiction Assistance Grant Program. Learn more.

We're making changes to better serve you

California has merged the three state cannabis authorities into a single, new Department of Cannabis Control.

Learn more

On this page

Rulemaking

Regulations are state laws with specific rules for how businesses and others must operate. The Department of Cannabis Control's (DCC) regulations are in California Code of Regulations, title 4, division 19.

DCC is taking steps to simplify the cannabis regulations.

Current regulations

Read the current DCC regulations:

https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220AB45

Date Published: 10/07/2021 02:00 PM

Assembly Bill No. 45

CHAPTER 576

An act to add and repeal Section 26013.2 of the Business and Professions Code, to amend Sections 11018.5, 100425, and 110065 of, to add Sections 110036, 110407, 110469, 110611, 111691, and 113091 to, to add Chapter 9 (commencing with Section 111920) to Part 5 of Division 104 of, and to repeal Section 111921.6 of, the Health and Safety Code, relating to industrial hemp, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor October 06, 2021. Filed with Secretary of State October 06, 2021.]

LEGISLATIVE COUNSEL'S DIGEST

AB 45, Aguiar-Curry. Industrial hemp products.

California – AB45

- Manufacturer of dietary supplements and food will have to register with the State Department of Public Health
- Demonstrate that all parts of the plant come from a state or country that has an established and approved industrial hemp program
  - Industrial hemp or cannabinoids, except cannabidiol
- The industrial hemp raw extract…does not exceed THC concentration of an amount determined allowable by the department in regulation, or the mass of the industrial hemp extract used in the final form product does not exceed a THC concentration of 0.3 percent

California – AB45

- Testing by independent laboratory
- Label: “THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY”
- A statement that cannabinoids should be kept out of reach of children
- The CA Department of Health may impose maximum serving sizes for hemp-derived cannabinoids, hemp extract and products derived therefrom, active cannabinoid concentration per serving size, the number of servings per container, and any other requirements it deems necessary

California – AB45

- "Industrial hemp product" does not include industrial hemp or a hemp product approved by FDA, or a hemp product that has received Generally Recognized As Safe (GRAS) designation
- For purposes of nonfood applications, "industrial hemp product" does not include a hemp product that contains derivatives, or compounds derived from the seed of industrial hemp
- Other interesting definitions:
  - (3) "Manufacturing" also includes processing, preparing, holding, or storing hemp components and ingredients
  - (4) "Manufacturing" does not include planting, growing, harvesting, drying, curing, grading, or trimming a plant

Questions?

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