AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

The 2018 Farm Bill and Hemp & Hemp-Derived Products (e.g. CBD)

3rd SoCal Dietary Supplement Consortium

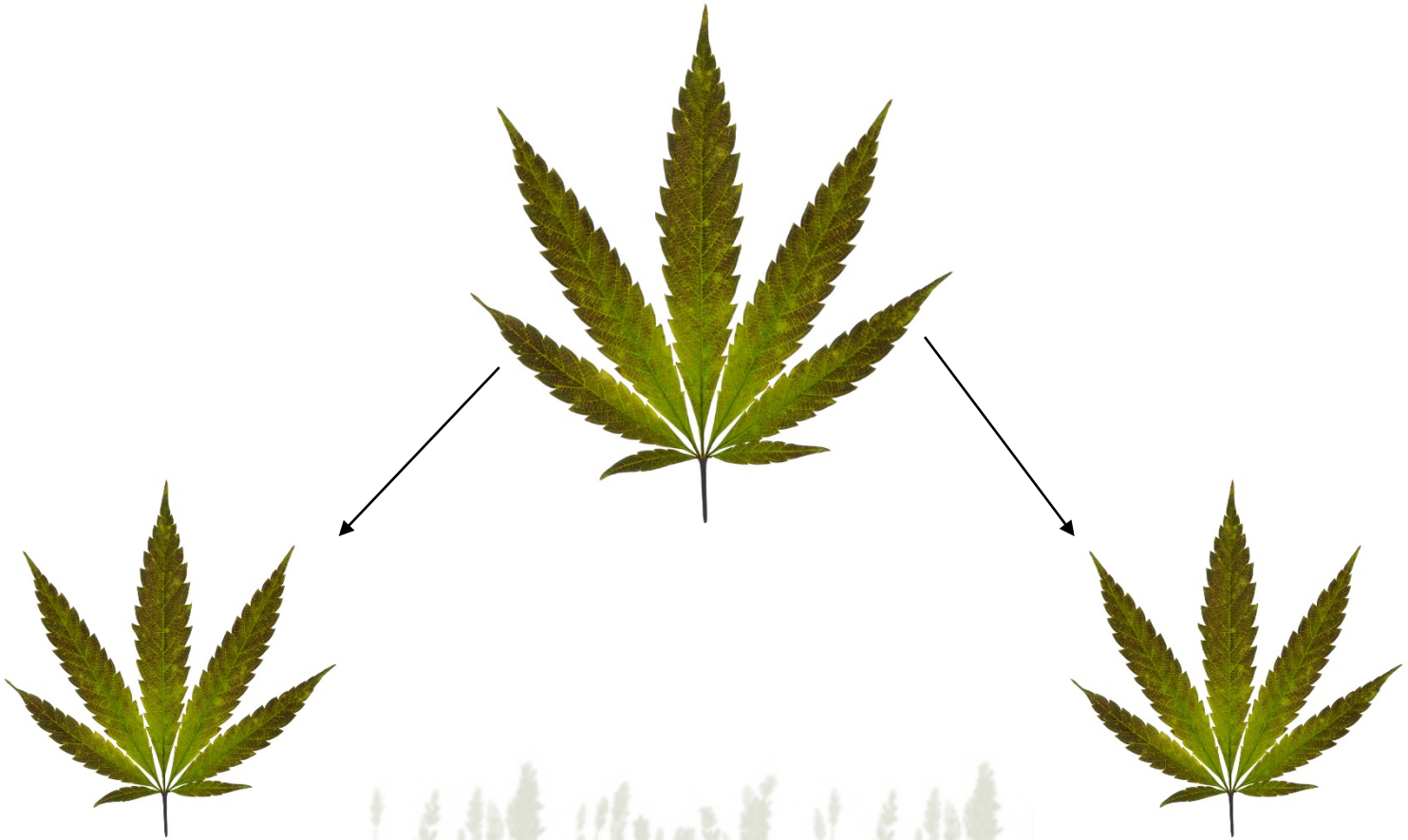
May 17, 2019

Michael McGuffin

President, American Herbal Products Association
mmcguffin@ahpa.org

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

Cannabis sativa L.



Marijuana

Hemp
[≤0.3% THC]

Cannabis sativa L.

Hemp
[≤0.3% THC]

Hemp Regulatory Controls: Historical

Hemp
[≤0.3% THC]

U.S. Department of Justice · Drug Enforcement Administration

FDA U.S. FOOD & DRUG ADMINISTRATION

Hemp Regulatory Controls: Post Farm Bill 2018

Hemp
[≤0.3% THC]

U.S. Department of Justice · Drug Enforcement Administration

FDA U.S. FOOD & DRUG ADMINISTRATION

USDA

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

Hemp Farming Act of 2018

- S. 2667 **(McConnell (R-KY); Wyden (D-OR); Merkley (D-OR); and Paul (R-KY))** / H.R. 5485 **(Comer (R-KY) and Polis (D-CO))**
- Included in Senate version of the Agriculture Improvement Act of 2018 (the "Farm Bill")
- Adopted in Conference
- Signed into law December 20, 2018

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

The Farm Bill and the CSA

- Amends the Agricultural Marketing Act
- "The term 'hemp' means 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."
- Hemp acknowledged as an agricultural commodity under the federal purview of USDA (e.g., crop insurance, etc.)
- Defines hemp "plans" to be submitted to USDA by States and Tribal governments.

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

The Farm Bill and the CSA

- Amends the Controlled Substances Act
  - "The term 'marihuana' means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin … does not include ***(i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946; or (ii)*** the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination."
  - "Tetrahydrocannabinols***, except for tetrahydrocannabinols in hemp…"*** [re: CSA Schedule I]

Hemp Regulatory Controls: Post Farm Bill 2018

Hemp
[≤0.3% THC]

U.S. Department of Justice · Drug Enforcement Administration

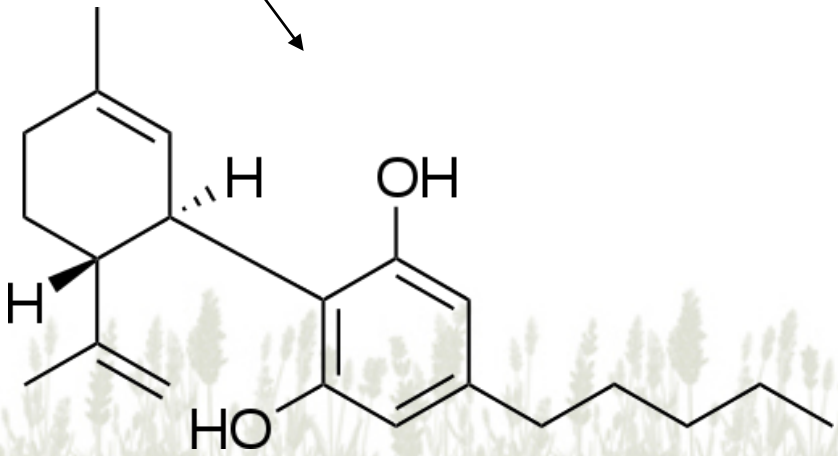
FDA U.S. FOOD & DRUG ADMINISTRATION

USDA

Hemp v. CBD under the FDCA

FDA U.S. FOOD & DRUG ADMINISTRATION

Hemp
[≤0.3% THC]



Cannabidiol (CBD)

Hemp under the FDCA

DS Ingredients 21 U.S.C. 321(ff)(1)

- (A) Vitamins
- (B) Minerals
- (C) **Herbs and other botanicals** (except tobacco)
- (D) Amino acids
- (E) Dietary substances for use by man to supplement the diet by increasing the total dietary intake
- (F) **Concentrates, metabolites, constituents, extracts, or combinations of the above**

Supplement regulations

- **Facility registration.** Register with FDA (every 2 years); applicable to manufacturing, labeling, packing, and holding operations (except home-based).
- **Ingredients.** Formulate products with dietary ingredients (vitamins, minerals, herbs and other botanicals, amino acids, dietary substances; concentrates, metabolites, constituents, extracts, combos of above).
- **Identity.** Name as dietary supplement or herbal or other characterizing form (e.g., “vitamin supplement”). Do not represent as a conventional foods (e.g., “snack”) or as a sole item of a meal or the diet.
- **Labels-Generally.** Label products with Supplement Facts; identify all ingredients; provide name and address of manufacturer or distributor; provide all information that is “material in light of … claims … and the consequences that may result from … use.”
- **Labels-Allergens.** Meet food label rule for major food allergens (milk, eggs, fish, Crustacean shellfish, peanuts, tree nuts, wheat, soy).
- **cGMP.** Manufacture, pack, label and hold products in accordance with current good manufacturing practice regulations (21 CFR 111).

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

Supplement regulations

FDA U.S. FOOD & DRUG ADMINISTRATION

- **Claim limits.** Allowance for statements of nutritional support ("structure-function" claims), nutrient content claims, and FDA approved health claims. No claims allowed to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.
- **Claim notification.** Notify FDA within 30 days of first marketing of structure function claims; assert substantiation on file for such claims.
- **Disclaimer.** "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
- **SAERs.** Submit all serious adverse event reports received to FDA; maintain records of all adverse event reports received.
- **Form and route.** Formulate products for oral ingestion as tablet, capsule, powder, softgel, gelcap, or in liquid form.
- **NDIs.** Submit premarket notifications to FDA, where required, regarding new dietary ingredient (post-1994) in any supplement**.**

Hemp under the FDCA

As a dietary supplement

- 321 (ff)(1)(C): The herb itself (any part)
- 321 (ff)(1)(F): Any concentrate, constituent, or extract [or metabolite or combination]
- **Marketers need to comply with the FDA regulations applicable to dietary supplements**

Hemp
[≤0.3% THC]

State issues???

Hemp under the FDCA

As a food or beverage

- Hemp seed oil and other derivatives have been freely used
- FDA has acknowledged GRAS status of de-hulled hemp seed, hemp seed oil, and hemp seed protein powder (for one company)
- **Marketers need to comply with the FDA regulations applicable to these product categories**

Hemp
[≤0.3% THC]

State issues???

Hemp under the FDCA

As a cosmetic / personal care ingredient

- Hemp seed oil and other derivatives have been freely used
- FDA has stated no restriction of prohibition (for “any cannabis or cannabis-derived ingredient”)
- **Marketers need to comply with the FDA regulations applicable to these product categories**

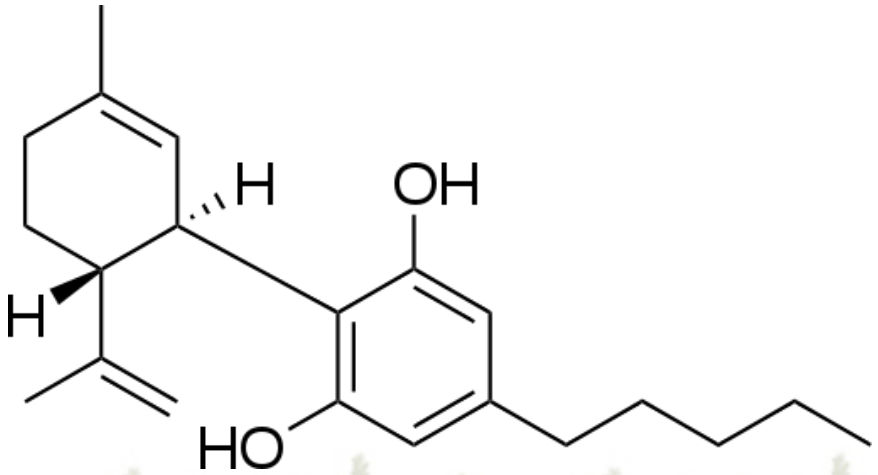
Hemp
[≤0.3% THC]

State issues???

CBD under the FDCA

As a dietary supplement or food ingredient:

- **It's complicated!**



Cannabidiol (CBD)

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers

www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers; Last updated 4/3/19

Q. Can THC or CBD products be sold as dietary supplements?

- A. No. Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B) of the FD&C Act. Under that provision, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 …, or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are excluded from the definition of a dietary supplement.

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers

www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers; Last updated 4/3/19

Q. Can THC or CBD products be sold as dietary supplements?

- There is an exception to section 201(ff)(3)(B) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD.
- FDA is not aware of any evidence that would call into question its current conclusions that THC and CBD products are excluded from the dietary supplement definition…. Interested parties may present the agency with any evidence that they think has bearing on this issue … review of information that has been submitted thus far has not called our conclusions into question.

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers

www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers; Last updated 4/3/19

Q. Can THC or CBD products be sold as dietary supplements?

- When a substance is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act, the exclusion applies unless FDA, in the agency's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the FD&C Act. To date, no such regulation has been issued for any substance.

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers

www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers; Last updated 4/3/19

Q. Can THC or CBD products be sold as dietary supplements?

- Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of this exclusion, and therefore might be able to be marketed as dietary supplements. However, all products marketed as dietary supplements must comply with all applicable laws and regulations governing dietary supplement products. For example, manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" … generally must notify FDA about these ingredients [and] include information demonstrating that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling.
- Numerous other legal requirements apply to dietary supplement products, including requirements relating to Current Good Manufacturing Practices (CGMPs) … and labeling.

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers

www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers; Last updated 4/3/19

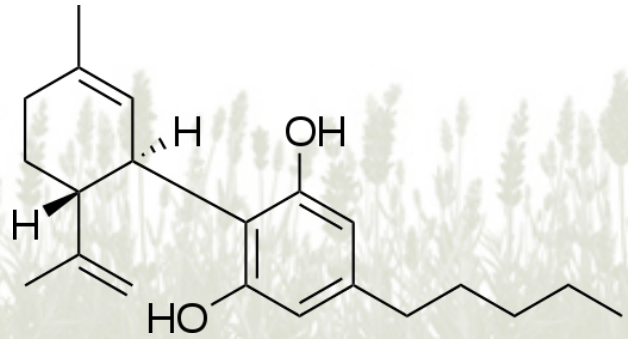
Q. Is it legal, in interstate commerce, to sell a food (inc. any animal food or feed) to which THC or CBD has been added?

- A. No. Under section 301(ll) of the FD&C Act, it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the Act or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. There are exceptions, including when the drug was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted or, in the case of animal feed, that the drug is a new animal drug approved for use in feed and used according to the approved labeling. However, based on available evidence, FDA has concluded that none of these is the case for THC or CBD.

CBD under the FDCA

Possible challenges

- What is the date on which the “prior-IND” was established?
  - IND authorized
  - Substantial clinical investigations
  - Publicly disclosed
- When did oral-dosage CBD products enter the market?
- Is the food or supplement “article” exactly the same as the prior-IND or drug “article”?
- When is CBD “added”?



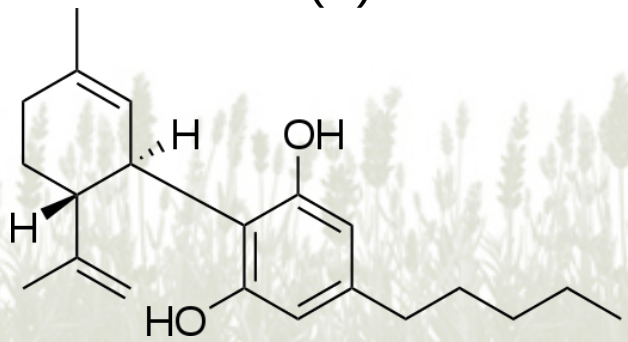
CBD under the FDCA

Authority of the Secretary HHS

- Exception to sections 201(ff)(3)(B)(i) and (ii) relevant to dietary supplements:

  "… unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter."

- NOTE: There is similar exception to sections 201(ll) relevant to conventional foods.



AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

CBD under the FDCA

Commissioner Gottlieb (Dec. 20, 2018)

- The Farm Bill's effects include "…removing hemp from the Controlled Substances Act…"
- "Congress explicitly preserved the agency's current authority to regulate products containing cannabis or cannabis-derived compounds."
- "… we continue to be concerned at the number of drug claims being made about products not approved by the FDA that claim to contain CBD or other cannabis-derived compounds."
- "Additionally, it's unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived … because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements."

CBD under the FDCA

Commissioner Gottlieb (Dec. 20, 2018)

- "…**pathways remain available for the FDA to consider whether there are circumstances in which certain cannabis-derived compounds might be permitted in a food or dietary supplement**. Although such products are generally prohibited to be introduced in interstate commerce, the FDA has authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement. We are taking new steps to evaluate whether we should pursue such a process. However, the **FDA would only consider doing so if the agency were able to determine that all other requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients**."
- "… we intend to hold a public meeting in the near future for stakeholders to share their experiences and challenges with these products, including information and views related to the safety of such products."

CBD under the FDCA

Commissioner Gottlieb (Feb. 27, 2019)

- "…**there is not a good proxy for us doing this through regulation**" NOTE: The statutory option that could allow FDA to permit an approved or investigational new drug as a food or supplement has never been applied in the decades it has existed.
- "…**we will come back and have a discussion with Congress [if] this is sufficiently complicated for the Agency [or] we make a determination that this will be a multi-year regulatory process**."
- **March 5, 2019: Commissioner Gottlieb announced his resignation from FDA, effective in 30 days.**

CBD under the FDCA

Commissioner Gottlieb (March 28, 2019)

Sen. Patrick Leahy: **"**How do you think FDA should use its enforcement discretion on the use of CBD as an ingredient?"

Dr. Gottlieb: **"We are using enforcement discretion right now.** I will take action against CBD products on the market if I consider what manufactures are making are over the line claims. So if you are marketing CBD and your claiming it can cure cancer or prevent Alzheimer's Disease, we are going to take action against that because that could misled a patient to forgoing otherwise effective therapy, but **there are products on the market right now that given our enforcement priorities and our limited resources, we haven't taken action against.** That's not an invitation for people to continue marketing these products – we are concerned about it."

CBD under the FDCA

Commissioner Gottlieb (March 28, 2019)

Dr. Gottlieb: "But we heard Congress loud and clear here. We know you want a pathway. Our regulatory scheme would be a challenging route because it not only exists as a drug in the marketplace but it is also under substantial clinical investigation. So even if there wasn't an approved drug because it was never previously in the food supply, we don't have a clear route to allow CBD to be lawfully marketed short of promulgating new regulations. That's why one of things the CBD working group at FDA … will be ***looking at what options we could propose to Congress to potentially legislate on this issue*** in a specific manner."

CBD under the FDCA

FDA Leadership in transition

HHS Secretary Azar (March 12, 2019) [announcing the appointment of Dr. Nathan Sharpless as Acting FDA Commissioner]: "We are going to be carrying forward Dr. Gottlieb's vision," Azar said. "His agenda is my agenda. My agenda is his agenda."

AHPA Policy (adopted March 2019)

- AHPA recommends that any manufacturer, labeler, packer, holder or marketer of dietary supplements or foods that contain hemp or CBD comply with the following federal regulations that apply to such operations: food facility registration; current good manufacturing and good agricultural practice regulations; labeling requirements, including nutrition labeling, allergen disclosure, listing of required contact information, absence of drug claims, etc.; new dietary ingredient and food additive provisions, where applicable; and also, that dietary supplement operations comply with applicable obligations for timely submission to FDA of any received serious adverse event reports associated with their products.
- Adopted to address misinterpretation that FDA's position on the lawful status of CBD implies these products are not regulated.

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

State rules vary widely

- Idaho, Louisiana, Ohio, Nebraska, South Dakota, and Texas take a restrictive approach to CBD.
- California, North Carolina, and South Carolina have adopted FDA's position that CBD cannot be used in foods.
- Several states (e.g., Oklahoma, Tennessee) only allow for the use of CBD under certain medical conditions; less clear for other uses.
- New York requires CBD products to be labeled and manufactured as a dietary supplement.
- Several states expressly allow hemp and CBD products, some with conditions:
  - Kansas has a 0% THC requirement for CBD products.
  - Indiana and Utah have unique labeling requirements; Utah also requires registration.
  - Several states (e.g., Michigan and Maine) allow the use of hemp products in foods.

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

THANK YOU!

Michael McGuffin

mmcguffin@ahpa.org

American Herbal Products Association

THE VOICE OF THE HERBAL PRODUCTS INDUSTRY