ARIZONA
DEPARTMENT OF
HEALTH SERVICES

Date: 11/21/2024

To: Arizona County Health Departments

From: Arizona Department of Health Services

Re: Requirements to Sell Kava and Other Dietary Supplement Products

There is a growing trend of licensed/permitted retail food establishments in Arizona that may be selling kava, CBD, and other dietary ingredient products or unapproved additives in a manner not in compliance with local, state, and federal laws. The Food and Drug Administration (FDA) considers kava to be a supplement that is limited to personal use. Unapproved food additives and ingredients such as kava are not designated Generally Recognized As Safe (GRAS) according to 21 CFR Part 170.30. Therefore, as with any additive or supplement that is not GRAS and/or consistent with all legal requirements, unapproved additives cannot be used in foods or beverages as an ingredient. Manufacturing, processing, packaging, or labeling of dietary supplements and dietary ingredients, as defined in 21 CFR §111.3 (including kava) must be done under the FDA Dietary Supplement Health and Education Act of 1994 (DSHEA) regulations and oversight.

Permitted retail food establishments shall ensure the separation of supplements and food. The following requirements are meant to help counties determine the line between food and supplements. Permitted retail food establishments wishing to sell these products shall comply with the following requirements and make corrective actions requested by the regulatory authority. County health departments shall address violations of the Arizona Administrative Code ("A.A.C."). Title 9, Chapter 8 during inspections pursuant to the county's delegated regulatory authority and ensure necessary corrective actions are taken by the establishment pursuant to the county's delegated regulatory authority.

- Kava, CBD, and other dietary ingredients, such as unapproved additives, shall only be sold as supplements.
- Kava, CBD, and other dietary ingredients/supplements/unapproved additives shall be obtained from suppliers with current FDA registrations for the production of supplements who are in good regulatory standing with 21 CFR Part 111.

- Kava, CBD, and other dietary ingredients/supplements/unapproved additives shall be obtained from the suppliers in hermetically sealed individual packages and sold to customers as is.
- Each kava, CBD, and dietary ingredients/supplements/unapproved additives package shall have proper supplement labeling per 21 CFR Part 101.36.
- Customers shall purchase the hermetically sealed individual packages of kava, CBD, and other dietary ingredients/supplements/unapproved additives from the business and the customers may add it to their foods or beverages at their discretion.
- Retail businesses shall not process, package, or otherwise handle bulk kava, CBD, and other dietary ingredients/supplements/unapproved additives.
- Retail businesses shall not use kava, CBD, and other dietary ingredients/supplements/unapproved additives as an ingredient in foods or beverages.
- Retail business employees shall not handle kava, CBD, and other dietary ingredients/supplements/ unapproved additives, except for selling hermetically sealed individual packages to customers.

The Arizona Department of Health Services encourages county health departments to make available to retailers and for the benefit of consumers and the general public, educational resources about the potential adverse effects or interactions associated with kava and other supplements. Examples of consumer advisory language include:

- General Messaging About Supplements: Individuals should consult with their physician before consuming any supplement. Some supplements may interact with other medications, food, alcohol, or other supplements. Some supplements may be harmful to pregnant women, fetuses, or children.
- General Messaging Regarding Kava:
    - The FDA advises consumers of the potential risk of severe liver injury -- including hepatitis, cirrhosis, and liver failure -- associated with the use of kava-containing dietary supplements. Kava has been shown to interact with other drugs, herbs, and dietary supplements and may lead to significant negative consequences Given these reports, persons who have liver disease or liver problems or persons who are taking drug products that can affect the liver should consult a physician before using kava-containing supplements. Additionally, children, pregnant, and breastfeeding individuals are not advised to consume kava, as studies have not confirmed the safety or extent of risk in these populations. Consumers who use a kava-containing dietary supplement and who experience signs of illness associated with liver disease (yellowing of skin, brown urine, nausea, vomiting, weakness) should seek medical attention.

- General Messaging Around CBD: https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis
    - The FDA has determined that CBD has the potential to cause adverse health risks, including liver injury, harm to the male reproductive system, gastrointestinal distress, changes in mood (most commonly experienced as irritability and agitation), and changes in alertness (most commonly experience as drowsiness or sleepiness). CBD has been shown to interact with other drugs, which may impact the effectiveness and side effects from those drugs. The risk is particularly concerning for children, people who are pregnant or breastfeeding, and people taking medications. Consumers are warned that unapproved CBD products may make therapeutic claims that have not been evaluated for quality, effectiveness, and safety. Consumers should seek medical attention for proper diagnosis, treatment, and care of medical conditions and if experiencing adverse effects from CBD consumption.

Please contact ADHS with any comments or questions at foodsafety@azdhs.gov.