

## KAVA (*Piper methysticum*)

### **Background**

Kava (*Piper methysticum*) is a perennial shrub native to the islands of the Pacific Ocean. It is harvested for its root stock, which contains the pharmacologically active compounds kavalactones. A number of cases of liver damage (hepatitis and cirrhosis), and liver failure have been associated with commercial extract preparations of kava. In 2002, the FDA issued an advisory alerting consumers and healthcare providers to the potential risk of liver-related injuries associated with the use of kava dietary supplements.

Source: FDA Consumer Advisory: [Kava-Containing Dietary Supplements May be Associated with Severe Liver Injury](#)  
(3/25/2002)

### **Regulatory Oversight**

The U.S. Food and Drug Administration (FDA) considers kava to be a supplement that is limited to personal use. Kava is not Generally Recognized as Safe (GRAS) according to 21 CFR Part 170.30 and therefore as with any supplement that is not GRAS, cannot be used in foods or beverages as an ingredient. Kava can only be manufactured, processed, packaged, and labeled as a supplement in a facility that is under the FDA or State regulatory oversight.

- 21 CFR 111 Link: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-111>
- GRAS List link: <https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras>

### **Requirements for retailers and manufacturers**

- Pursuant to federal guidance (21 CFR 111), kava may only be sold as a supplement, and may only be obtained from suppliers with current permits for the production of supplements. Kava shall be obtained from the suppliers in hermetically sealed individual packages and sold to customers as is.
- Each kava package must have proper supplement labeling, per 21 CFR Part 101.36.
- To the extent kava is being added to food or beverages, it may only added to the food or beverages by customers, at their own discretion, after purchasing the kava from hermetically sealed, individual packages..
- Retail businesses shall not process, package, or otherwise handle bulk kava.
- Retail businesses shall not use kava as an ingredient in foods or beverages.
- Retail business employees shall not handle kava, except for selling hermetically sealed individual packages of kava to customers.

### **Regulatory Action**

If any of the above requirements are not adhered to, businesses may be subject to enforcement action such as a cease-and-desist order or a suspension of their permit by the appropriate local or state authority. Regulations: NAC 446.0105, NRS 446. 880

