

MEMORANDUM

Date: August 2019

To: Denver Retail Businesses Selling Kava Products

From: Denver Department of Public Health & Environment (DDPHE), Public Health Investigations Division

Re: Requirements to Sell Kava Products

It has recently come to DDPHE's attention that Denver retail businesses selling kava products may not be 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. 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/or labeled as a supplement in a facility that is under FDA regulatory oversight.

To compliantly sell kava, Denver retail businesses shall meet the following requirements:

- Kava shall only be sold as a supplement.
- Kava 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 shall be obtained from the suppliers in hermetically sealed individual packages and sold to customers as is.
- Each kava package shall have proper supplement labeling, per [21 CFR Part 101.36](#).
- A conspicuous consumer advisory statement shall be provided that reads, *"Please be advised that consuming kava products may pose a risk to consumers and is not recommended for use by persons under 18 years of age or by pregnant or breastfeeding women. Kava is not recommended to be used with alcoholic beverages. More information is available upon request."* This consumer advisory statement can be affixed to each kava package label or provided on a conspicuously placed sign or menu board.
- The following additional information shall always be available upon customer request at the business, either on a sign or menu board, or printed out for customers: *"A potential risk of rare, but severe, liver injury may be associated with kava-containing dietary supplements. Ask a health care professional before use if you have or have had liver problems, frequently use alcoholic beverages, or are taking any medication. Stop use and see a doctor if you develop symptoms that may signal liver problems, including jaundice (yellowing of the skin or whites of the eyes) and brown urine. Other nonspecific symptoms can include nausea, vomiting, light-colored stools, unusual tiredness, weakness, stomach or abdominal pain, and loss of appetite. Not for use by persons under 18 years of age, or by pregnant or breastfeeding"*

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women. Not for use with alcoholic beverages. Excessive use, or use with products that cause drowsiness, may impair your ability to operate a vehicle or heavy equipment.”

- Customers shall purchase the hermetically sealed individual packages of kava from the business and the customers shall add it to their foods or beverages at their discretion.
- 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.

If any of the above requirements are not adhered to, Denver businesses may be subject to enforcement action such as a cease and desist order or a general violation court summons under the authorities granted in the [Denver Food Establishment Rules and Regulations](#) and/or [Chapter 23 of the Denver Revised Municipal Code](#). Denver business shall have thirty (30) days from receipt of this memorandum to comply with these requirements.

Please contact DDPHE with any comments or questions at phicomments@denvergov.org

Kind regards,

Danica Lee
Division Director

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