WASHOE COUNTY
HEALTH DISTRICT
ENHANCING QUALITY OF LIFE

Public Health
Prevent. Promote. Protect.

Food Protection Hearing and Advisory Board
Meeting Notice and Agenda

Members
Michael Chaump
Lanaii K. Elkins
J.P. Pinocchio
Jay Rathmann
Christopher Romm
Christopher Thompson
Rose Wolterbeek

Wednesday, July 26, 2023
1:00 p.m.

Washoe County Administration Complex, Building B
Health District South Conference Room
1001 East Ninth Street
Reno, NV

An item listed with asterisk (*) next to it is an item for which no action will be taken.
1:00 p.m.

1. ***Roll Call and Determination of Quorum**
2. ***Pledge of Allegiance**
3. ***Public Comment**
   Any person is invited to speak on any item on or off the agenda during this period. Action may not be taken on any matter raised during this public comment period until the matter is specifically listed on an agenda as an action item.
4. **Approval of Agenda – (<u>For possible action</u>)**
   July 26, 2023
5. **Approval of Draft Minutes – (<u>For possible action</u>)**
   February 25, 2020
6. Public Hearing to consider the appeal of the Health District's decision to prohibit the addition of kava (Piper methysticum) to foods or beverages per Section 050.050 of the Regulations of the Washoe County District Board of Health Governing Food Establishments. **Case #1-23FP - (For possible action)**
   Staff Representative: Robert Fyda

7. *Board Comment

Limited to announcements or issues for future agendas.

8. *Public Comment

Any person is invited to speak on any item on or off the agenda during this period. Action may not be taken on any matter raised during this public comment period until the matter is specifically listed on an agenda as an action item.

9. Adjournment – (For possible action)

Possible Changes to Agenda Order and Timing. Items on the agenda may be taken out of order, combined with other items, withdrawn from the agenda, moved to the agenda of another later meeting; moved to or from the Consent section, or they may be voted on in a block. Items with a specific time designation will not be heard prior to the stated time, but may be heard later. Items listed in the Consent section of the agenda are voted on as a block and will not be read or considered separately unless withdrawn from the Consent agenda.

Special Accommodations. The Food Protection Hearing and Advisory Board Meetings are accessible to the disabled. Disabled members of the public who require special accommodations or assistance at the meeting are requested to notify Administrative Health Services in writing at the Washoe County Health District, 1001 E. 9th St, Reno, NV 89512, or by calling 775.328.2416, 24 hours prior to the meeting.

Public Comment. During the "Public Comment" items, anyone may speak pertaining to any matter either on or off the agenda, to include items to be heard on consent. For the remainder of the agenda, public comment will only be heard during items that are not marked with an asterisk (*). Any public comment for hearing items will be heard before action is taken on the item and must be about the specific item being considered by the Board. In order to speak during any public comment, each speaker must fill out a "Request to Speak" form and/or submit comments for the record to the Recording Secretary. Public comment for individual agenda items is limited as follows: three minutes for individual speakers.

Response to Public Comment. The Food Protection Hearing and Advisory Board can deliberate or take action only if a matter has been listed on an agenda properly posted prior to the meeting. During the public comment period, speakers may address matters listed or not listed on the published agenda. The *Open Meeting Law* does not expressly prohibit responses to public comments by the Food Protection Hearing and Advisory Board. However, responses from the Board members to unlisted public comment topics could become deliberation on a matter without notice to the public. On the advice of legal counsel and to ensure the public has notice of all matters the Food Protection Hearing and Advisory Board will consider, Board members may choose not to respond to public comments, except to correct factual inaccuracies, ask for Health District Staff action or to ask that a matter be listed on a future agenda. The Food Protection Hearing and Advisory Board may do this either during the public comment item or during the following item: "Board Comments – Limited to Announcement or Issues for future Agendas."

Posting of Agenda; Location of Website.

Pursuant to NRS 241.020, Notice of this meeting was posted at the following locations:

Washoe County Health District, 1001 E. 9th St., Reno, NV
Reno City Hall, 1 E. 1st St., Reno, NV
Sparks City Hall, 431 Prater Way, Sparks, NV
Washoe County Administration Building, 1001 E. 9th St, Reno, NV
Downtown Reno Library, 301 S. Center St., Reno, NV
Washoe County Health District Website www.washoecounty.us/health
State of Nevada Website: https://notice.nv.gov

How to Get Copies of Agenda and Support Materials. Supporting materials are available to the public at the Washoe County Health District located at 1001 E. 9th Street, in Reno, Nevada. Ms. Susy Valdespin, Administrative Secretary to the District Board of Health is the person designated by the Washoe County District Board of Health to respond to requests for supporting materials. Ms. Rogers is located at the Washoe County Health District and may be reached by telephone at (775) 328-2415 or by email at svaldespin@washoecounty.us. Supporting materials are also available at the Washoe County Health District Website www.washoecounty.us/health pursuant to the requirements of NRS 241.020.

WASHOE COUNTY
HEALTH DISTRICT
ENHANCING QUALITY OF LIFE

Public Health
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Food Protection Hearing and Advisory Board
Meeting Minutes

Members
Christopher Romm, Chair
Sergio Guzman
Michael Chaump
David DeMars
J.P. Pinocchio
George Heinemann
Christopher Thompson

Tuesday, February 25, 2020
1:00 p.m.

Washoe County Administration Complex, Building B
Health District South Conference Room
1001 East Ninth Street
Reno, NV

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1. *Roll Call and Determination of Quorum

Chair George Heinemann called the meeting to order at 1:00 pm.

The following members and staff were present:

Members present: Sergio Guzman
J.P. Pinocchio
George Heinemann
Christopher Thompson

Members absent: Christopher Romm
Michael Chaump
David DeMars

Ms. Valentin verified a quorum was present

Staff present: Dania Reid, Washoe County District Attorney
Charlene Albee, Environmental Health Division Director
Amber English, Environmental Health Specialist Supervisor
Latricia Lord, Senior Environmental Health Specialist
Mike Touhey, Senior Environmental Health Specialist

2. *Pledge of Allegiance

Chair Heinemann led the pledge to the flag.

3. *Public Comment

None.

4. Approval of Agenda - February 25, 2020

Chair Heinemann moved to approve the agenda for the February 25, 2020, Food Protection Hearing and Advisory Board meeting with a correction of item number 5. The date for Approval of Draft Minutes corrected to July 9, 2019, instead of July 17, 2019. Mr. Guzman seconded the motion which was approved four in favor and none against.

5. **Approval of Draft Minutes -** July 9, 2019

Chair Heinemann moved to approve the minutes for the July 9, 2019, Food Protection Hearing and Advisory Board meeting. Mr. Pinocchio seconded. Call to vote – Motion carried.

6. **Public Hearing to consider Staff's Recommendation for Approval of Variance Case No. 1-20FP Rocky Mountain Chocolate Factory Application for Variance to Sections 200.005 (Outdoor food establishment, applicable requirements), 060.205(A) (Food equipment, certification and classification) and 070.020 (Plumbing system) of the Regulations of the Washoe County District Board of Health Governing Food Establishments. Case #1-20FP**

Staff Representative: Latricia Lord

Ms. Lord stated that Board Member's packets contained staff recommendations, and documentation outlining the circumstances leading to this request for appeal. She was the inspector for the past several years for the Greater Nevada Field. She provided a brief background on the agenda item and offered to answer questions.

Mr. Pinocchio asked where the location was within the park and if this was the only vendor affected.

Ms. Lord responded there was only one other and is located at the end of the mezzanine near the grassy area. The current set up had been recently reclassified as an outdoor food establishment. When first opened in 2010 it was categorized as a permanent snack bar. Regulations were recently revised and a new category added. The establishment meets the outdoor establishment more closely.

Mr. Pinocchio inquired if it was the same as a temporary booth.

Ms. Lord stated it was permitted as permanent but with the new change in regulations it requires additional requirements to meet the current regulations.

Mr. Pinocchio inquired with Greg of Rocky Mountain Chocolate Factory if their self-contained unit is at capacity, have they made arrangements to refill and get rid of the graywater?

Greg responded that the unit is serviced every home stand (3-4 game stretch). They have plans for 4-8 hours. It is serviced every time as well as the display unit. Our 8-foot deli case holds up to 330 caramel apples at temperature. Everything gets cleaned and wiped down between home stands. The mop bucket is 10 feet away from the booth, making disposing greywater, mixing clean water with bleach, and then refilling with clean water for hand washing convenient. Everything is wiped down as we are outside. If we didn't do that we would invite pests.

Mr. Heinemann asked how far away they were from the water supply and dumping.

Greg responded they are only 10 feet away.

Mr. Thompson inquired if Greg had any problems with these recommendations.

Greg responded he did not and felt they were fair and just.

Findings of Fact:

1. **Can the proposed operation of the food establishment avoid endangering the health and safety of persons living in the Washoe County Health District, if this variance is granted?**
   The proposed operation can be conducted in such a way as to avoid endangering the health and safety of persons living in or visiting the Washoe County Health District. Consequently, the Health District is supportive of the variance request. Our support is predicated on the inclusion of and strict adherence to the conditions provided in our recommendation below.
2. **Would compliance to these Regulations produce a hardship on the applicant without equal or greater benefit to the public?**
   The applicant has indicated that compliance with the Regulations would require either moving from their long-standing location or the addition of plumbing infrastructure and both could create significant financial hardship. While the Health District believes compliance with the Regulations provides benefit to the public, approval of the variance and recommended conditions and strict adherence to those conditions will provide an equal benefit.
3. **Will the owners of property in the general vicinity of the food establishment be adversely affected if this variance is approved?**
   The owners of property in the general vicinity will not be adversely affected if this variance is approved.

Recommendation:

Staff recommends that the Board advise the District Board of Health to grant the variance contingent on strict adherence to the following conditions:

1. The fresh and gray water tanks in the portable hand sink must always be maintained per the Operational Plan and manufacture's recommendations.
2. All staff working in this food establishment must be able to verbalize to WCHD inspectors the provisions described in the Operational Plan.
3. No changes to the foodservice operations or menu are allowed without prior approval from WCHD.
4. Rocky Mountain Chocolate Factory must maintain full compliance with all conditions. Failure to maintain compliance may result in the revocation of the variance at which time full compliance with Sections 200.005, 060.205 (A), and 070.020 will be required.

Motion:

Mr. Thompson moved to recommend that the District Board of Health approve Rocky Mountain Chocolate Factory's variance request providing Rocky Mountain Chocolate Factory comply with conditions 1 - 4 as presented in the staff report. Chair Heinemann seconded. Call to vote – Motion carried.

7. **Public Hearing to consider Staff's Recommendation for Approval of Variance Case No. 2-20FP Levy Premium Food Service Application for Variance to Sections 200.005 (Outdoor food establishment, applicable requirements), 060.205(A) (Food equipment, certification and classification) and 070.020 (Plumbing system) of the regulations of the Washoe County District Board of Health Governing Food Establishments.**
   Staff Representative: Latricia Lord

Ms. Lord explained she was inspecting establishments and handed out information on proposed regulations on utilizing portable hand sinks. Went through similar process as the previous variance. She stated she made the mistake that they didn't need a heater when they do (**070.030)**. She handed out information on the Elite Pro Services portable hot water handwashing sink. Ms. Lord stated they have purchased two of these units which are on their way and are similar to the Rocky Mountain Chocolate Factory. They weren't completely contained to one portable unit (multiple units). Gave options to stay self-contained, get variance, or get a permanent hand sink. If they were to install plumbed hand sinks it would cause significant financial hardships. We support this variance as long as they follow their operational plan.

Chair Heinemann if they were going to change the menu what would the timeline be?

Ms. Lord stated it was a conversation with the inspectors. Being at the ballpark they typically schedule a menu for the whole season and do not roll out new items until the next season. They might do small modifications but are good at contacting our inspectors.

Mr. Pinocchio stated he did not understand the variance. They have the right to do business within their facility so if we're talking about a hand sink option, they have a home base. How many feet from the home base can they go?

Ms. Lord replied that once they become an outdoor food establishment, they must be within 50 feet of a supporting brick and mortar structure to supply but it also needs its own hard plumbed sink.

Ms. English added if outside of permitted restaurant, you would need a temporary food permit or some other categorization.

Mr. Pinocchio inquired if there is something that allows them to go so far away from home base and still operate.

Ms. English stated it would be the same as your restaurant. If you were to set up a booth outside at your restaurant, you wouldn't be able to operate without an additional permit. There is no distance allowable.

Mr. Thompson asked if the food from the outside from outside goes back into the restaurant, can it be sold.

Ms. English stated the only other category we have is a BBQ operation. That is very limited to they would have to submit an operational plan, but they couldn't have POS or sides inside so that doesn't fit what they are doing either. A smoker outside is allowed with an operational plan but sales must be made inside.

Findings of Fact:

1. **Can the proposed operation of the food establishment avoid endangering the health and safety of persons living in the Washoe County Health District, if this variance is granted?**
   The proposed operation can be conducted in such a way as to avoid endangering the health and safety of persons living in or visiting the Washoe County Health District. Consequently, the Health District is supportive of the variance request. Our support is predicated on the inclusion of and strict adherence to the conditions provided in our recommendation below.

2. **Would compliance to these Regulations produce a hardship on the applicant without equal or greater benefit to the public?**
   The applicant has indicated that compliance with the Regulations would require significant capital improvements to install the applicable plumbing infrastructure and that would create significant financial hardship. While the Health District believes compliance with the Regulations provides benefit to the public, approval of the variance and recommended conditions and strict adherence to those conditions will provide an equal benefit.
3. **Will the owners of property in the general vicinity of the food establishment be adversely affected if this variance is approved?**
   The owners of property in the general vicinity will not be adversely affected if this variance is approved.

Recommendation:

Staff recommends that the Food Protection Hearing and Advisory Board advise the District Board of Health to grant the variance contingent on strict adherence to the following conditions:

1. The fresh and gray water tanks in all portable hand sinks must always be maintained per the Operational Plan and manufacturer's recommendations.
2. All staff working in any Outdoor Food Establishment operated by Levy Premium Food Service must be able to verbalize to WCHD inspectors the provisions described in the Operational Plan.
3. No changes to any foodservice operations or menu at any Outdoor Food Establishment operated by Levy Premium Food Service is allowed without prior approval from WCHD.
4. Levy Premium Food Service must maintain full compliance with all conditions. Failure to maintain compliance may result in the revocation of the variance at which time full compliance with Sections 200.005, 060.205 (A) and 070.020 will be required.

Motion:

Mr. Thompson moved to recommend that the District Board of Health approve Levy Premium Food Services' variance request providing Levy Premium Food Service comply with conditions 1 - 4 as presented. Chair Heinemann seconded. Call to vote – Motion carried.

8. **Discussion and possible action to establish a regular schedule for future Food Protection Hearing and Advisory Board Meetings as needed.**
   Staff Representative: Charlene Albee

Charlene introduced Dania Reid, our new District Attorney and stated that in order to coordinate schedules, she was proposing to set up regular monthly meetings. The meetings were previously on the 1st Thursday of the month. The last two meetings ended up on Tuesday. We propose that three weeks in advance we would inform you if the meeting is cancelled.

Mr. Pinocchio stated he would like to be an alternate due to his busy season schedule coming up. He then inquired where Dania Reid came from.

Ms. Reid explained she works for the Washoe County District Attorney's office and provided a short background.

Ms. Albee requested board member recommendations. Discussion ensued and the first Tuesday of every month at 1pm was the final determination. She stated our agency would like to at least commit to a meeting in February of every year to touch base on updates and changes. She also suggested having elections at that point to have a Chair/Vice Chair for the year. This would create some structure moving forward. Ms. Albee stated, once we have appointments, we could provide public meeting training to the board members.

Chair Heinemann stated he liked the idea.

Mr. Thompson expressed that it would make the meetings run smoother.

Ms. Reid stated if there is another meeting before February 2021, we could agendize elections/nominations.

Chair Heinemann commented that he thought an annual meeting is a great idea.

Motion:

Chair Heinemann moved to establish the first Tuesday of every month as a standing meeting for the Food Protection Hearing and Advisory Board. Mr. Thompson seconded. Call to vote – Motion carried.

9. *Board Comment

There was no Board Comment.

10. *Public Comment

As there was no one wishing to speak, Chair Heinemann closed the Public Comment period.

11. Adjournment –

Chair Heinemann adjourned the meeting at 3:38 p.m.

WASHOE COUNTY
HEALTH DISTRICT
ENHANCING QUALITY OF LIFE

DD_____
DHO_____

Staff Report
Board Meeting Date: July 26, 2023

TO: Food Protection Hearing and Advisory Board

FROM: Amber English, Environmental Health Specialist Supervisor
775-433-4015, aeenglish@washoecounty.gov

SUBJECT: Public Hearing to consider the appeal of the Health District's decision to prohibit the addition of kava (*Piper methysticum*) to foods or beverages per Section 050.050 of the Regulations of the Washoe County District Board of Health Governing Food Establishments. Case #1-23FP

Authority to hold hearing on appeals:

Pursuant to Section 240.105 (A) of the regulations of the Washoe County District Board of Health Governing Food Establishments (food establishment regulations), the Food Protection Hearing and Advisory Board (Hearing Board) shall hold hearings to consider appeals to staff decisions which adversely affect said person in any manner.

District Health Strategic Objective supported by this item: Healthy Environment – Create a healthier environment that allows people to safely enjoy everything Washoe County has to offer.

APPLICABLE REGULATIONS:

010.015 "Adulterated food" defined. "Adulterated food" has the meaning ascribed in Nevada Revised Statutes (NRS) 585.300 through 585.310. A food shall be deemed adulterated if:

A. It bears or contains any poisonous or deleterious substance which may render it injurious to health unless the substance is not an added substance and the quantity of the substance does not ordinarily render it injurious to health;

B. It consists in whole or in part of a diseased, contaminated, filthy or decomposed substance, or if it is otherwise unfit for food;

C. It has been produced, prepared, packed or held under unsanitary conditions whereby it may have become contaminated with filth or rendered diseased, unwholesome or injurious to health;

D. It is the product of an animal which is diseased, died otherwise than by slaughter or was fed upon the uncooked offal from a slaughterhouse;

E. Its container is composed, in whole or in part, of any poisonous or deleterious substance, which may render the contents injurious to health;

F. It bears or contains any color additive, which is unsafe within the meaning of the Federal Act;

G. Any valuable constituent has been in whole or in part omitted or abstracted there from;

H. Any substance has been substituted wholly or in part therefore;

I. Damage or inferiority has been concealed in any manner; or

J. Any substance has been added thereto or mixed or packed therewith to increase bulk or weight or reduce its quality or strength, or make it appear better or of greater value than it is.

010.275 "Food" defined. "Food" means any food, drink, confection or beverage, or any component in the preparation or manufacture thereof, intended for ultimate human consumption, stored, being prepared or manufactured, displayed, offered for sale, sold, or served in a food establishment or temporary food establishment (NRS 446.017).

For the purpose of these regulations, water and ice served or offered in a food establishment, and chewing gum, are considered food.

010.280 "Food additive" defined. "Food additive" means any substance, the intended use of which results directly or indirectly, in it's becoming a component or otherwise affecting the characteristics of food.

A. "Food additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(s) and 21 CFR 170.3(e)(1).

B. "Color additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR 70.3(f).

050.005 Safe, unadulterated, and honestly presented

All food must be free from spoilage, filth, adulteration, misbranding, contamination and as specified under Section 050.345, honestly presented, and safe for human consumption.

050.050 Additives

Food may not contain unapproved food additives or additives that exceed amounts specified in law. Food ingredients and sources of radiation, or pesticide residues shall not exceed provisions specified in law.

050.370 Discarding or reconditioning unsafe, adulterated, or contaminated food

A. A food that is unsafe, adulterated, or not honestly presented as specified in Section 050.005 must be discarded or reconditioned according to an approved procedure.

B. Food that is not from an approved source as specified in Sections 050.010 - 050.040 must be discarded.

C. Ready-to-eat food that may have been contaminated by an employee who has been restricted or excluded must be discarded.

D. Food that is contaminated by food employees, consumers, or other persons through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means must be discarded.

050.345 Honestly Presented

A. Food must be offered for human consumption in a way that does not mislead or misinform the consumer.

B. Food or color additives, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a food.

PREVIOUS ACTION

The use of kava as a food ingredient is prohibited in all food establishments regulated by the Washoe County Health District (WCHD) and the State of Nevada Department of Health and Human Services (NDHHS). Additional information on the use of kava can be found on NDHHS website: https://dpbh.nv.gov/Reg/Trending_EHS/Trending_Health_Topics/

On November 4, 2022, the WCHD received a City of Reno business license for Reno Roots Kava and Tea Bar. Staff contacted the applicant and informed the applicant to submit applicable building plans, and to apply for a health permit to operate a food establishment.

On December 19, 2022, the WCHD received building plans from the City of Reno for the modifications to a building located at 935 N Virginia Street with a proposed business name of Reno Roots Kava and Tea Bar. Staff assigned to review the building plans put them on hold with comments back to the submitter to address several items before the plans could proceed through the review process. One of the comments included the prohibition of adding kava to food or beverage products (see Attachment A).

Revised building plans were received by WCHD on January 9, 2023, and staff again put the plans on hold pending the submittal of additional information. The comment regarding the prohibition of adding kava to food or beverage products was again included in the comments back to the submitter on January 19, 2023, and WCHD staff offered to have an in-person meeting to review requirements for the establishment (see Attachment B).

On January 24, 2023, WCHD staff met with the owner of Reno Roots Kava and Tea Bar, Neil Cavanagh to review the outstanding plan review/construction issues and to further explain the reasons kava is not allowed to be added as an ingredient in food products. In addition to reviewing equipment and establishment construction requirements, the following information was provided to Mr. Cavanagh during this meeting:

- Retail food establishments operating in Washoe County are subject to provisions in the WCHD food establishment regulations which are consistent with the federal Food and Drug Administration (FDA) Food Code and the federal Food, Drug and Cosmetic Act (FD&C Act).
- The food establishment regulations prohibit unapproved additives, or supplements that are not Generally Recognized as Safe (GRAS) by the FDA from being added as an ingredient to food. Kava is currently not listed on the FDA's GRAS substances database.
- Based on current regulations, Reno Roots Kava and Tea Bar's proposal to add kava directly to water to serve as tea to consumers is a prohibited activity since supplements that are not GRAS are limited to personal use and cannot be added to foods or beverages (including water) as an ingredient.
- WCHD staff offered the following alternative solutions that are in line with State of Nevada guidance and FDA Food Code which would allow Mr. Cavanagh to sell kava tea without violating provisions of the WCHD food establishment regulations:
    - Obtain kava supplements from an approved source and sell the kava tea supplement in hermetically sealed individual packages with appropriate labeling where the consumer can purchase the supplement and add it to their own beverage.
    - Contact the agency that has regulatory oversight over supplement manufacturing in Washoe County, NDHHS and explore options to be permitted as a supplement manufacturer.

During the meeting, Mr. Cavanagh stated that he obtains his kava from an FDA approved source in Florida. WCHD staff asked that he provide this documentation for review. Additionally, Mr. Cavanagh stated that he is aware of other Washoe County food establishments adding kava to foods/beverages and stated there is an approved kava bar in Las Vegas. He was informed that Southern Nevada Health District (SNHD) is a separate jurisdiction with their own regulations, and we cannot speak to the details of establishments adding kava as food ingredient in their jurisdiction. WCHD staff also informed Mr. Cavanagh of the process to submit an anonymous complaint for WCHD to investigate any non-compliant establishment in Washoe County. However, WCHD staff was not aware of any other Washoe County facilities currently adding kava to foods/beverages but mentioned that one of the facilities mentioned by Mr. Cavanagh (The Studio) had been investigated and issued cease and desist notices by WCHD in the past. During the meeting, Mr. Cavanagh showed WCHD staff a letter written by a SNHD employee. The letter was addressed to an operator of a food establishment in Las Vegas and provided approval for the source of a packaged kava but did not address or discuss the use or approval of kava as an ingredient in food.

After the meeting with Mr. Cavanagh, WCHD did not receive any formal complaints from Mr. Cavanagh of other Washoe County facilities serving kava as an ingredient and did not receive FDA source documentation that was requested from Mr. Cavanagh for the Florida kava manufacturing facility that was being sourced. Mr. Cavanagh did send several emails to WCHD

staff including:

- An email from Mr. Cavanagh including a letter and statements on kava from the owner of the kava facility in Las Vegas and an article by Tyler Blythe posted by the American Kava Association stating their legal analysis regarding FDA's classification of kava (Attachment C).
- Emails asking WCHD staff to provide regulatory information from Washoe County, City of Reno, and the State of Nevada stating the prohibition on the possession or sale kava in Washoe County, and a copy of the legislative digest of AB 303 regarding kratom, another herbal supplement that is not FDA GRAS listed (Attachment D).
- An email from Mr. Cavanagh with an excerpt from Johns Hopkins Medicine, Herbal Medicine fact webpage (Attachment E).

WCHD staff reached out to SNHD and State of Nevada staff to enquire about their regulations regarding the use of kava as a food / beverage ingredient. The following is a summary of their responses:

- SNHD staff responded via email that they found the State of Nevada and FDA specifically identified CBD and kratom as unapproved but did not include kava and therefore this was probably a reason for the approval of the kava facility in Las Vegas (Attachment F). However, the staff member who wrote the email was not directly involved in the situation.
- During follow-up phone conversations between WCHD staff and SNHD staff, it was determined that SNHD did not have updated information from the FDA on the use of kava in food when they made the decision to allow a kava tea bar. SNHD staff is in the process of reviewing the information WCHD has received from both FDA and NDHHS.
- The NDHHS provided a flyer regarding the use of kava as a food / beverage ingredient at retail (Attachment G) which is consistent with WCHD regulations and options proposed to the applicant.

On February 21, 2023, the WCHD received an objection letter from Mr. Cavanagh's attorney requesting the WCHD permit Mr. Cavanagh to serve kava tea (Attachment H). The WCHD staff and Legal staff reviewed the contents of the letter and determined there was no additional regulatory information provided by Mr. Cavanagh's legal counsel that would alter the determination originally made by WCHD staff that the Regulations of the Washoe County District Board of Health Governing Food Establishments do not allow kava as an ingredient in foods / beverages.

To move forward with the opening of his establishment, Mr. Cavanagh submitted his final establishment menu without kava being included as an option. On February 27, the WCHD issued the health permit for Reno Roots located at 935 N Virginia Street. WCHD staff verbally reviewed the appeal process for food establishments and written appeal instructions are included on the inspection report form (Attachment I).

On March 31, 2023, WCHD issued a final response to the objection letter received by Mr. Cavanagh's legal counsel upholding the original decision made by WCHD to prohibit kava being added to food or beverage products (Attachment J).

In an effort to find a solution for the safe use of kava as an ingredient in foods or beverages, on June 1, 2023, the WCHD submitted and inquiry to the FDA Food and Cosmetic Information Center

Technical Assistance Network to receive guidance on the process for Reno Roots to obtain a GRAS letter for the safe use of kava as a food ingredient and for any updated scientific information on the safe use of kava. The FDA responded that the kava was not eligible for GRAS status and provided the reasons why (Attachment K).

On June 12, 2023, WCHD staff met with Mr. and Mrs. Cavanagh and Reno Councilman / Washoe County District Board of Health Vice Chair, Devon Reese to again discuss the options for serving kava tea in the establishment. Mr. Cavanagh demonstrated the process he would like to use to serve kava tea in the traditional format. This process included adding a portion of bulk kava root powder to a strainer bag that is then inserted into a container of water and kneaded to strain the water through the kava root powder. Mr. Cavanagh stated he used the traditional documented kava powder calculation to measure the amount of kava root that is added to each batch. WCHD staff explained that since kava was a supplement and not on the GRAS list that this method was not an option under the Regulations of the Washoe County District Board of Health Governing Food Establishments but provided several potential options that would be allowed:

- Obtain kava supplements from an approved source and sell the kava tea supplement in hermetically sealed individual packages with appropriate labeling where the consumer can purchase the supplement, read the label (including warning labels and dosage amount), and add it to water served by the establishment.
- Contact the agency that has regulatory oversight over supplement manufacturing in Washoe County, NDHHS and explore options to be permitted as a supplement manufacturer.

Additional discussions included an explanation by WCHD staff on the Nevada legislative process and the process to appeal any decision made by the WCHD. Mr. and Mrs. Cavanagh indicated they would like to begin selling the individually packaged and labeled kava root that customers can add to their own beverage and asked what would be required by WCHD to move forward with this option. WCHD staff informed Mr. and Mrs. Cavanagh they would need to provide documentation of approved source (FDA or State supplement manufacturing operation registration number, or inspection documentation) to the WCHD for the individually wrapped supplements and receive approval from WCHD prior to selling the product.

In a follow-up email to WCHD after the meeting on June 12, 2023, Mr. Cavanagh asked for information on the next step to submit an appeal to the Hearing Board. On June 15, 2023, Mr. Cavanagh was provided with information on the appeal process, and he responded by indicating he would like to move forward with an appeal to the decision made by WCHD during the meeting on June 12, 2023 (See Attachment L).

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. Currently, kava root has been classified as a supplement and is not listed on the GRAS substances database by the FDA.

In general, dietary supplements are introduced to market without any safety evaluation. Due to the Dietary Supplement Health and Education Act of 1994, most supplements are not approved by the FDA before they are marketed, and dietary supplement firms are not required to provide evidence related to safety before or after they market products. Dietary supplements can be introduced to market without any safety evaluation by the FDA. Dietary supplements are available for purchase in many retail grocery stores for personal use where the consumer can read the labels of the products, consult with their health care provider, and make an informed choice on the use and dosage of the product.

The Food Drug and Cosmetic Act (FD&C) is based on the current science and require that any substance that is added to food is subject to premarket review and approval by FDA, unless the substance is generally recognized, by qualified experts, as having been adequately shown to be safe under conditions of its intended use (GRAS substance database). Kava has not met this requirement per the information contained in the FDA's Post-market Determinations that the Use of a Substance is not GRAS (Attachment K).

The Washoe County Food Establishment Regulations are based on the safety standards of the FDA Food Code which are based on best practices and sound science in order to ensure that food served to the public meets safety standards and help reduce outbreaks of foodborne illness and injury.

WCHD staff found informational document regarding the current beneficial uses of kava and the associated safety concerns and risks with kava consumption as well susceptible populations issued by the U.S Department of Health and Human Services National Institute of Health (Attachment M).

FINDINGS OF FACT:

The Hearing Board may recommend to the District Board of Health to uphold, modify, or rescind the Health District's decision to prohibit the addition of kava (*Piper methysticum*) to foods or beverages as requested by the applicant if, after a hearing on due and proper notice, it determines by a preponderance of evidence the following:

1. Strict application of the regulation would result in exceptional and undue hardship to the person requesting the appeal; and
2. The appeal, if granted, would not:
    a. Cause substantial detriment to the public health; or
    b. Substantially impair the purpose of that regulation.

RECOMMENDATION

Based on the record of the hearing, staff recommends the Hearing Board make a finding of one of the following:

1. The Hearing Board could recommend that the District Board of Health uphold the decision to prohibit the addition of kava to foods or beverages per Section 050.050 of the Regulations of the Washoe County District Board of Health Governing Food Establishments.
2. The Hearing Board could recommend that the District Board of Health modify the decision

to prohibit the addition of kava to foods or beverages per Section 050.050 of the Regulations of the Washoe County District Board of Health Governing Food Establishments.

3. The Hearing Board could recommend that the District Board of Health rescind the Health District's decision to prohibit the addition of kava to foods or beverages per Section 050.050 of the Regulations of the Washoe County District Board of Health Governing Food Establishments

POSSIBLE MOTIONS

1. "Move to recommend to the District Board of Health to sustain the Health District's decision to prohibit the addition of kava to foods or beverages per Section 050.050 of the Regulations of the Washoe County District Board of Health Governing Food Establishments."
2. "Move to recommend to the District Board of Health to modify the Health District's decision to prohibit the addition of kava to foods or beverages per Section 050.050 of the Regulations of the Washoe County District Board of Health Governing Food Establishments with the following amended or additional conditions..."
3. "Move to recommend to the District Board of Health to rescind the Health District's decision to prohibit the addition of kava to foods or beverages per Section 050.050 of the Regulations of the Washoe County District Board of Health Governing Food Establishments and approve Mr. Cavanagh's appeal to allow him to add kava to foods or beverages."

Cancel Reports Help

Task
Health Food Review
Due Date
01/05/2023
Assigned Date
12/19/2022
Assigned to Department
WCHD EHS Inspectors
Assigned to
Briana E Johnson
Status
On Hold
Action by Department
WCHD EHS Inspectors
Action By
Briana E Johnson
Status Date
12/23/2022
Start Time
End Time
Hours Spent
3.0
Time Tracking Start Date
Overtime
No
Est. Completion Date
In Possession Time (hrs)
Comments
The above referenced plan has been put on hold. The following issues must be properly addressed prior to further review and approval by WCHD:

1. Complete and submit the Food Establishment Review Application (including a menu) and turn in with revision. See the following link: https://www.washoecounty.gov/health/files/ehs/forms/environmental/H-450_Food_Est_Plan_Review_Ap.pdf.
2. Provide a more detailed floor plan with the anticipated equipment layout. This includes but is not limited to refrigeration, plumbing, sinks, preparation tables, water fill stations, beverage heating stations, seating, build out of walls/structures, and storage areas.
3. Submit all Equipment Spec sheets for review.
4. Provide a finish schedule for all materials in facility – floors, ceiling, and walls.
5. Provide plumbing plan indicating how and where all equipment is draining. Please provide plumbing details, cut sheets on all equipment which has plumbing and indicate the use type for all equipment. All fixtures and associated drainage must be shown. Be advised that a direct connection may not exist between the sewage system and a drain originating from equipment in which food, portable equipment, or utensils are placed.
6. At least one (1) mop sink or one (1) curbed cleaning facility equipped with a floor drain must be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste. Please note that lavatories or sinks normally used for preparing food or washing utensils or equipment may not be used for this purpose.
7. Provide location of any dry storage areas.
8. Plan mentions an existing water heater in the basement. Indicate whether the basement will be utilized for any food/beverage preparation or storage for the facility.
9. ***Please note that retail businesses shall not use kava as an ingredient in foods or beverages. 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 is not included on the GRAS database, therefore, as with any supplement that is not GRAS, it cannot be used in foods or beverages as an ingredient. Kava may only 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.

The permittee must submit permit revisions to the original permit intake department. The original permit intake department will send permit revisions to WCHD for review.

Comments were entered 12/23/2022 and emailed to the primary contact on record for the permit.

Please contact WCHD at ehsplanreview@washoecounty.gov for plan status or questions regarding review. All emails must include the building permit number in the subject line.

Billable
No

Task Specific Information

Plan Reviewer	Phone Number
Briana Johnson	775-900-7231

Cancel **Reports** **Help**

Task
Health Food Review
Due Date
01/10/2023
Assigned Date
01/09/2023
Assigned to Department
WCHD EHS Inspectors
Assigned to
Briana E Johnson
Status
On Hold
Action by Department
WCHD EHS Inspectors
Action By
Briana E Johnson
Status Date
01/19/2023
Start Time
End Time
Hours Spent
3.5
Time Tracking Start Date
Overtime
No
Est. Completion Date
In Possession Time (hrs)
Comments
With respect to the proposed project, these notes identify additional information needed to complete the review process:

1. Equipment Spec sheets for the instant hot water heater, refrigeration unit, tea warmer and ice machine must be included for review. These sheets must include make and model numbers and be NSF approved for commercial use in a food establishment.
2. The plan shows two prep tables, however a barrier between the customer area and the kitchen space/prep tables was not shown. A barrier must be installed that is smooth, easily cleanable, durable and non-absorbent. The barrier must be sized to prevent potential contamination of any consumable food or drinks and/or the food preparation surface.
3. It is unclear what the space on the south wall between the ice bin and hand sink going to be used for. Please clarify.
4. Provide a more detailed plumbing plan with the anticipated equipment layout. This includes but is not limited to drawing and labeling all hot and cold water lines to all applicable equipment (e.g. ice machines, dump sinks, hand sinks, water heaters, 3-compartment sink, restroom sinks, mop sinks, backflow devices, etc.) in addition to the associated drain lines for all applicable equipment and where they will be drained to. Be advised that a direct connection may not exist between the sewage system and a drain originating from equipment in which food, portable equipment, or utensils are placed. Include the location of all water fill stations, beverage heating stations, and the build out of walls/structures/service counters (if applicable).
5. Provide a more detailed finish schedule for all materials in facility – floors, ceiling, and walls. Include details on the flooring material in all areas of the facility. A photo provided by the owner showed wooden floors up against a floor sink. All wooden floors must be sealed with no open gaps. Additionally, the plans noted that the ceiling is composed of drywall. If drywalled, the ceiling must be properly sealed (e.g. semi-gloss paint or another material with a similar sealed finish).
6. ***Please note that retail businesses shall not use kava as an ingredient in foods or beverages. 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 is not included on the GRAS database, therefore, as with any supplement that is not GRAS, it cannot be used in foods or beverages as an ingredient. Kava may only 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.
Billable
No

Attachment C

From: Johnson, Briana
To: English, Amber E.
Subject: FW: Reno Roots Kava and Tea Bar
Date: Tuesday, May 9, 2023 11:53:53 AM
Attachments: 47807265-v2-Kava Time - Letter to Southern Nevada Health District regarding Kava.DOCX

Briana Johnson, REHS
Environmental Health Specialist | Environmental Health | Washoe County Health District
BEJohnson@washoecounty.gov | C: (775) 900-7231 | 1001 E. Ninth St., Bldg. B, Reno, NV 89512

WASHOE COUNTY HEALTH DISTRICT
ENHANCING QUALITY OF LIFE

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WashoeEats.com

Please consider the environment before printing this e-mail.

From: Neil Cavanagh <neilcavanagh1@yahoo.com>
Sent: Tuesday, January 24, 2023 5:49 PM
To: Johnson, Briana <BEJohnson@washoecounty.gov>; Collins, Byron <bcollins@washoecounty.gov>
Subject: Reno Roots Kava and Tea Bar

[**NOTICE:** This message originated outside of Washoe County -- **DO NOT CLICK** on **links** or open **attachments** unless you are sure the content is safe.]

Good evening and thank you for your time today, it was nice to be able to see whom I have been communicating with. Attached is a letter from a friend who owns the Kava bar in Las Vegas. There is quite a bit of information that I hope will help in granting me the ability to serve Kava Tea. I look forward to hearing from you.

There seems to be confusion as to how the FDA views Kava in its various forms. FDA has been known to tell bars, restaurants, and health bars that they consider kava to be a dietary supplement and therefore it is subject to the regulations set forth in the Dietary Health and Education Act of 1994. The FDA argues that since it is not a traditional part of the American diet prior to 1994, that it falls under the DHSEA regulations which classify Kava as a Dietary Supplement rather than a traditional food (beverage).

There are several issues with the FDA's position. First, Kava has a 3,000-year history of use in Polynesian culture. There are over 1.5 million people of Polynesian heritage living within the United States a large population of who have been drinking Kava since their major migration in the 1950's. In fact, the last state to be added to

the union was Hawaii in 1959; an island with nearly ½ million Polynesians who regularly drank and continue to drink Kava as part of their diet and culture. Hawaii was added to the Union in 1959, and as such, if there was any doubt about Kava being a regular part of the American diet as a food or beverage, a few hundred thousand Kava drinkers became Americans that year. Thus, Kava is clearly grandfathered in under the 1994 DHSEA as a traditional beverage (food) and is therefore not a dietary supplement or a new dietary ingredient and thus not subject to Dietary Supplement regulations such as the FDA's maximum recommended daily dose of Kavalactones.

Kava was recognized not only as a food long before 1994, but also as a medicine in the most prominent medical compendium of its time, the King's American Dispensatory, published in 1898 by Harvey Wickes Felter, M.D., and John Uri Lloyd, Phr. M., Ph. D. If the FDA does not wish to recognize the Kings American Dispensatory as an official medical authority, then it can surely find Kava in part 2 of the 1950 official American Dispensatory under Ganosan and Neurocardin.

The FDA's attempt to classify the traditionally prepared beverage Kava Kava as a dietary supplement is an attempt to impose Kavalactone limitations and labeling requirements in a similar manner to dietary supplements in order to negatively impact the establishments revenue generating ability. For the following reasons, traditionally prepared Kava as it is served in this establishment does not meet the FDA's own criteria to classify it as a Dietary Supplement.

From the Federal Food, Drug, and Cosmetic Act (FD&C Act)
Section 321

(ff) The term "dietary supplement"—

(1) means a product (other than tobacco) intended to supplement the diet that bears or
contains one or more of the following dietary ingredients:
(A) a vitamin.
(B) a mineral.
(C) an herb or other botanical.
(D) an amino acid.
(E) a dietary substance for use by man to supplement the diet by increasing the total dietary
intake; or
(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described
in clause (A), (B), (C), (D), or (E);

AND

(2) means a product that—
(A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or
(ii) complies with section 411(c)(1)(B)(ii);
(B) is not represented for use as a conventional food or as a sole item of a meal

or the diet;
and
(C) is labeled as a dietary supplement; and

AND

(3) does—
(A) include an article that is approved as a new drug under section 505 or licensed as a
biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to
such approval, certification, or license, marketed as a dietary supplement or as a food unless
the Secretary has issued a regulation, after notice and comment, finding that the article, when
used as or in a dietary supplement under the conditions of use and dosages set forth in the
labeling for such dietary supplement, is unlawful under section 402(f); and
(B) not include—
(i) an article that is approved as a new drug under section 505, certified as an antibiotic under
section 507 7, or licensed as a biologic under section 351 of the Public Health Service Act (42
U.S.C. 262), or
(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which
substantial clinical investigations have been instituted and for which the existence of such
investigations has been made public, which was not before such approval, certification,
licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary,
in the Secretary's discretion, has issued would be lawful under this Act.
Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food
within the meaning of this Act.

Analysis:
For traditionally prepared Kava to fall under the FDA's dietary supplement regulations, including labeling requirements and Kavalactone limits, it must first clearly meet the FDA's definition of a dietary supplement. To meet the FDA's definition it must meet all three sections. The following analyzes the traditionally prepared form of Kava as it pertains to these three sections.

Section 1
Kava is a botanical and therefore meets the criteria for section 1c.

Section 2

Kava does not meet the criteria for section 2b if it is represented for use as a conventional food, such as a traditional Polynesian tea served in an open (unsealed) container such as a cup or bowl. Kava's on-site preparation, its representation as a "tea" and its open and unsealed container servings, meets the definition of a conventional food, rather than a dietary supplement. Furthermore, Kava has the following nutritional value: The majority of dried kava root is comprised of carbohydrates of which 40% is starch, 20% fiber, 3% simple sugars, 3.5% protein and 3.5% minerals. The remaining 30% of dried Kava root is comprised of fats and resins, which include the active constituents, Kavalactones. Therefore, it is clear that Kava roots have significant caloric and nutritional value as a conventional food item and if served as such, it does not meet the FDA definition of a dietary supplement under this section.

While the traditionally prepared Kava beverage has already been shown exempt under section 2, Section 3 will be analyzed for thoroughness below.

Section 3

Section 3(ii) states that the definition of a dietary supplement does not include "…an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted…". There have been many pharmaceutical preparations of Kava over the years which include LI 150®, WS1490®, that have been patented for use in clinical applications as listed below. Furthermore, these substantial clinical investigations have been made public under the following prestigious journals, thereby fulfilling the definition of Section 3bii in its entirety:

Effect of a special kava extract in patients with anxiety-, tension-, and excitation states of non-psychotic genesis. Double blind study with placebos over 4 weeks (PMID:1930344)
Journal of Phytomedicine -Volume 10, Supplement 4, 2003, Pages 38–49

Kava-Kava extract LI 150 is as effective as Opipramol and Buspirone in Generalized Anxiety Disorder – An 8-week randomized, double-blind multi-center clinical trial in 129 out-patients. Journal of Phytomedicine – Volume 10, Supplement 4, 2003, Pages 38–49

Corrigendum to "Clinical efficacy of kava extract WS® 1490 in sleep disturbances associated with anxiety disorders. Results of a multicenter, randomized, placebo-controlled, double-blind clinical trial" [J. Affect. Disord. 78 (2004) 101–110]
Journal of Affective Disorders, Volume 83, Issues 2–3, December 2004, Page 287

For the purpose of this analysis, Kava's application as an investigational drug under section 3 is irrelevant, though it is important to note an alternate classification for Kava such that it may be represented in a manner that exempts it from the FDA's definition of a dietary supplement.

The FDA's definition of a dietary supplement under the Federal Food, Drug, and Cosmetic Act (FD&C Act) Section 321 SS 2B is clear and traditionally prepared Kava beverages clearly do not meet the FDA's definition. The representation of Kava as a

traditional Polynesian Tea qualifies it as a conventional food item rather than a dietary supplement Therefore, when Kava is served in its traditionally prepared beverage form in an open container, it is not subject to the FDA's labeling and proposed Kavalactone limitations that are imposed upon Kava Kava containing dietary supplements.

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Neil Cavanagh
7\72.777.0234

VENABLE LLP

600 MASSACHUSETTS AVE., NW WASHINGTON, DC 20001
T 202.344.4000 F 202.344.8300 www.Venable.com

Todd H. Halpern
T 202.344.4152
F 202.344.8300
thhalpern@venable.com

October __, 2019

Via FedEx
and E-mail: **[INSERT E-MAIL ADDRESS]**

[INSERT CONTACT AND ADDRESS]

Re: Kava Tea

Dear **[INSERT CONTACT NAME]**:

We write on behalf of our client Kava Time, Inc. ("Kava Time"), the owner of 9th Island Kava, regarding its application for a Health Permit from the Southern Nevada Health District ("SNHD"). It is our understanding that our client is attempting to open a café where kava teas will be served, but that SNHD believes that kava may may not be used in food, because it is neither an approved food additive nor generally recognized as safe ("GRAS") for addition to food under the Food Code. However, this message fundamentally misunderstands the applicable law. When used in its traditional preparation as a tea, Kava is not a food additive but the food itself. Consequently, kava is not subject to the food additive provisions of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act" or the "Act") or the Food Code as set forth in your e-mail correspondence.

The Act defines "food" as "articles used for food or drink for man or other animals." *See* FD&C Act § 201(f)(1). In contrast, a food additive is defined as a substance that is added to a food that is not otherwise GRAS or a dietary ingredient. *See* FD&C Act § 201(s). The difference between a food and food additive is simple. The former does not require an approval under the FD&C Act or the Food Code, while the latter does require approval unless it is GRAS or a dietary ingredient. For instance, consumers may consume dried kava root or leaf in its pure or traditional form without kava being considered a food additive. The argument that seeping kava root in water transforms the kava into a food additive is without merit and contrary to the case law. Indeed, when courts have looked at this distinction in other but similar contexts, the courts have ruled that it strains credulity to find that a food is a food additive when the other ingredients in the product are merely the vehicle for consumption. This point is illustrated by *United States v. 29 Cartons of Black Currant Oil, An article of Food,* 987 F.2d 33 (1st Cir. 1993) and *United States v. Two Plastic Drums, More or Less of Food Labeled Black Currant Oil*, 984 F.2d 814 (7th Cir. 1993) reh'g denied, 1993 U.S. App. LEXIS 6742 (7th Cir. Mar. 31, 1993).

Both cases involved multi-ingredient foods that consisted as their main component of black currant oil ("BCO") which was to be encapsulated in glycerin and gelatin. The GRAS status of the latter two ingredients was not in dispute. Rather, the issue presented to both courts

is whether BCO is an unapproved food additive. The FDA argued that the BCO was a food additive because it was being added to the finished capsule and, thus, was an unapproved food additive that the agency did not believe was GRAS. In essence, the FDA was arguing that the GRAS ingredients were the food and BCO was the additive. Both courts rejected FDA's spurious argument, as the purpose of the capsule was to simply provide a delivery method for the oil. Specifically, the courts found that adding BCO to the capsule simply did not cause it to lose its characteristics as a food. Rather, the courts found the capsule was only intended as a means of ingesting the BCO. As the First Circuit noted:

> [t]he proposition that placing a single ingredient food product into an inert capsule as a convenient method of ingestion converts that food into a food additive perverts the statutory text, legislative intent, and defenestrates common sense. We cannot accept such anfractuous reasoning.

Applying both courts' reasoning to kava tea, seeping kava root in water is simply a convenient and traditional method of ingesting the kava, as the water does not change the basic characteristic of the root and serves no other purpose than to provide a means to enjoy the kava. In other words, kava is the food, not an additive to water, as black currant oil was not an additive to glycerin and gelatin. Accordingly, kava root seeped in water and consumed as a food is not subject to the food additive provisions of the FD&C Act and the provision of the Food Code that you cited in your e-mail.

We further note that even if kava root were being sold as a dietary supplement at the restaurant, it would not be prohibited from doing so. Indeed, many herbal dietary supplements are sold as teas, as that is one of the traditional methods of consuming the herbals. We are unaware of any statement from the FDA that dietary supplements cannot be consumed as teas. The few warning letters we were able to locate only objected to certain claims being made about the teas. More simply stated, there is nothing within the FD&C Act or the Food Code that states a dietary supplement cannot be prepared and consumed at a restaurant, coffee house, smoothie bar, tea bar, or any other establishment that sells food. Many of these establishments specifically permit customers to add dietary ingredients to their beverages in order to give health-conscious individuals another means of consuming their dietary supplements. We seriously doubt that the state plans to take action against every establishment that permits consumption of dietary ingredients on its premises, and to specifically single out kava root and tea would be a clear case of arbitrary and capricious behavior on the state's part. In the end analysis, there is simply no law or regulation that prohibits this practice.

Finally, this action by the state is costing our client a considerable amount of damages. This baseless decision to reject the application is causing significant delay of the opening date. Meanwhile, it continues to incur rent and other costs without any means for earning revenue. Moreover, our client's reputation within the community has been significantly tarnished by the SNDH's unjustified action, and those damages continue to mount every day. Our client prefers

to resolve this matter amicably; however, it is prepared to take all available legal action at its disposal to defend its rights to open a café where it can serve its clientele kava tea.

We trust this letter provides you with a sound basis to grant our client's application and permit it to sell kava tea there. Please let us know if you have any questions or would like to set up a time to discuss this matter.

Best regards,

Todd H. Halpern
Todd A. Harrison
Counsel to Kava Time, LLC

cc: **[ADD]**

Attachment D

From: Johnson, Briana
To: English, Amber E.; Collins, Byron; Touhey, Michael; Hadlock, Griffin; English, James
Subject: FW: Reno Roots Tea Bar
Date: Wednesday, January 25, 2023 11:56:50 AM

See the email below.

Briana Johnson, REHS
Environmental Health Specialist | Environmental Health | Washoe County Health District
BEJohnson@washoecounty.gov | C: (775) 900-7231 | 1001 E. Ninth St., Bldg. B, Reno, NV 89512

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WashoeEats.com

Please consider the environment before printing this e-mail.

From: Neil Cavanagh <neilcavanagh1@yahoo.com>
Sent: Wednesday, January 25, 2023 11:54 AM
To: Johnson, Briana <BEJohnson@washoecounty.gov>; Collins, Byron <bcollins@washoecounty.gov>; Dalice Cavanagh <dcavanagh71@yahoo.com>
Subject: Reno Roots Tea Bar

[**NOTICE:** This message originated outside of Washoe County -- **DO NOT CLICK** on **links** or open **attachments** unless you are sure the content is safe.]

Good morning, I am need of some information to help me locate information that your team has asked for. Your team had asked me to find any paperwork from the FDA, State, and any other governing entities about the sale of Kava. I am asking you the same, can you please provide me information from WCHD, City of Reno, and Nevada State showing that we cannot possess, sell, add to water, sell prepackaged product. This will help me locate information needed. Also your team brought up Kratom, I am attaching Nevada state bill AB303 that the Governor passed in 2019. I am confused why your team would make assumptions that this product is illegal. If it is illegal please send me the NRS, NV Bill, etc. showing that it is. Thank you in advance.

Neil Cavanagh

Assembly Bill No. 303–Assemblymen Wheeler and Yeager CHAPTER..... AN ACT relating to public health; prohibiting the sale of certain kratom products to a minor; prohibiting the preparation, distribution, advertising or sale of certain adulterated kratom products; prohibiting the sale of a kratom product that does not have a label that contains certain information; providing civil penalties; and providing other matters properly relating thereto. Legislative Counsel's Digest: Section 4 of this bill prohibits: (1) a person from knowingly selling or offering to sell kratom products to a child who is less than 18 years of age; (2) the sale of certain adulterated kratom products; and (3) the sale of a kratom product that does not include

a label that clearly sets forth the ingredients and directions for the safe and effective use of the kratom product. Section 4 also establishes a civil penalty of $1,000 for violating those provisions and defines a “kratom product.” EXPLANATION – Matter in bolded italics is new; matter between brackets [omitted material] is material to be omitted. THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS: Sections 1-3. (Deleted by amendment.) Sec. 4. Chapter 597 of NRS is hereby amended by adding thereto a new section to read as follows: 1. A person shall not knowingly sell or offer to sell any material, compound, mixture or preparation containing a kratom product to a child under the age of 18 years. 2. A person shall not knowingly prepare, distribute, advertise, sell or offer to sell a kratom product that is adulterated with a substance that affects the quality or strength of the kratom product to such a degree as to render the kratom product injurious to a consumer. A person has not violated the provisions of this subsection if he or she can show by a preponderance of evidence that he or she relied in good faith upon the representations of a manufacturer, processor, packer or distributor of the kratom product. 3. A person shall not sell a kratom product that does not have a label that clearly sets forth the ingredients and directions for the safe and effective use of the kratom product. – 2 – - 80th Session (2019) 4. A person who violates any provision of this section is subject to a civil penalty of not more than $1,000 for each violation. 5. As used in this section, “kratom product” means any product or ingredient containing: (a) Any part of the leaf of the Mitragyna Speciosa plant if the plant contains the alkaloid mitragynine or 7-hydroxymitragynine; or (b) A synthetic material that contains the alkaloid mitragynine or 7-hydroxymitragynine, Ê regardless of whether the product or ingredient is labeled or sold for human consumption.

From:	English, Amber E.
To:	English, Amber E.
Subject:	RE: Reno Roots Kava Bar
Date:	Thursday, July 20, 2023 12:57:59 PM

From: Collins, Byron <bcollins@washoecounty.gov>
Sent: Thursday, January 26, 2023 7:29 AM
To: Touhey, Michael <mtouhey@washoecounty.gov>
Cc: English, Amber E. <AEEnglish@washoecounty.gov>; Johnson, Briana <BEJohnson@washoecounty.gov>
Subject: FW: Reno Roots Kava Bar

FYI

Byron Collins, REHS
Senior Environmental Health Specialist | Environmental Health Services | Washoe County Health District
Bcollins@washoecounty.gov | O: (775) 328-2434 opt #8| 1001 E. Ninth St., Bldg. B, Reno, NV 89512

WASHOE COUNTY HEALTH DISTRICT
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Public Health

From: neilcavanagh1@yahoo.com <neilcavanagh1@yahoo.com>
Sent: Wednesday, January 25, 2023 7:48 PM
To: Johnson, Briana <BEJohnson@washoecounty.gov>; Collins, Byron <bcollins@washoecounty.gov>
Subject: Reno Roots Kava Bar

[**NOTICE:** This message originated outside of Washoe County -- **DO NOT CLICK** on **links** or open **attachments** unless you are sure the content is safe.]

Good evening Briana and Byron I am in need of the date, the agenda, the minutes, the ordinance, and names of the county commisioners who agreed the ban of kava and kratom in Washoe County please. Thank you in advance.

Neil
772.777.0234

Sent from Yahoo Mail on Android

Attachment E

From: Johnson, Briana
To: English, Amber E.
Cc: Collins, Byron
Subject: FW: Kava
Date: Friday, February 10, 2023 8:09:44 AM

Per Neil's request, see the email below.

Briana Johnson, REHS
Environmental Health Specialist | Environmental Health | Washoe County Health District
BEJohnson@washoecounty.gov | C: (775) 900-7231 | 1001 E. Ninth St., Bldg. B, Reno, NV 89512

WASHOE COUNTY HEALTH DISTRICT
ENHANCING QUALITY OF LIFE

Please take our customer satisfaction survey by clicking here

WashoeEats.com

Please consider the environment before printing this e-mail.

From: Neil Cavanagh <neilcavanagh1@yahoo.com>
Sent: Thursday, February 9, 2023 6:23 PM
To: Johnson, Briana <BEJohnson@washoecounty.gov>; Collins, Byron <bcollins@washoecounty.gov>
Subject: Kava

[**NOTICE:** This message originated outside of Washoe County -- **DO NOT CLICK** on **links** or open **attachments** unless you are sure the content is safe.]

Can you please forward this to Amber English. Thanks.

The FDA considers herbal supplements foods, not drugs. Therefore, they are not subject to the same testing, manufacturing, and labeling standards and regulations as drugs.

What are herbal supplements? Products made from botanicals, or plants, that are used to treat diseases or to maintain health are called herbal products, botanical products, or phytomedicines. **A product made from plants and used solely for internal use** is called an herbal supplement

Sent from Yahoo Mail on Android

Attachment F

From: Johnson, Briana
To: English, Amber E.; Touhey, Michael
Subject: Fwd: Follow up with Kava
Date: Tuesday, January 31, 2023 10:56:06 AM

FYI see the email below from the inspector down at SNHD.

Briana

Get Outlook for iOS

From: Jessica Ward <wardj@SNHD.ORG>
Sent: Tuesday, January 31, 2023 9:58:54 AM
To: Johnson, Briana <BEJohnson@washoecounty.gov>
Subject: Follow up with Kava

[**NOTICE:** This message originated outside of Washoe County -- **DO NOT CLICK** on **links** or open **attachments** unless you are sure the content is safe.]

Good morning Briana,

For your questions regarding Kava, I want to refer you to our Regulartory Support Office supervisor, Christine Sylvis.
She responded to our Kava facility when it first came about, so she will be able to help you a lot more than when I can offer you.
You can reach out to her via email at SYLVIS@SNHD.ORG

For the question regarding the difference between kava vs kratom or CBD, we found that the state and FDA specifically identified kratom and CBD to be unapproved but not for kava.
This probably was another reason for us to approve the usage of kava.

Sorry I couldn't be more helpful but I hope everything works out for you!

I'll let Christine know that you will be reaching out to her.

Best,

SNHD Southern Nevada Health District

Our Mission: To assess, protect, and promote the health, the environment, and the well-being of Southern Nevada communities, residents, and visitors.

Jessica Ward, REHS
Environmental Health Specialist II
Southern Nevada Health District
280 S. Decatur Blvd.
Las Vegas, NV 89107
http://www.southernnevadahealthdistrict.org/ferl/index.php

This message may contain privileged and confidential information intended solely for the use of the addressee. If you are not the intended recipient, you should immediately stop reading this message and delete it from your system. Please notify me at wardj@snhd.org* or 702-759-1110 *if you have received this message in error. Any unauthorized reading, distribution, copying. Or other use of this message or its attachments is strictly prohibited. This message may not be copied or distributed without this disclaimer.

Please consider the environment before printing this e-mail

Attachment G

Nevada Division of Public and Behavioral Health – Environmental Health Section

KAVA (*Piper methysticum*)

Background

Kava (*Piper methsticum*) 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

NEVADA DIVISION OF PUBLIC AND BEHAVIORAL HEALTH
ENVIRONMENTAL HEALTH SECTION
Phone: 775-684-5280
Website: https://www.dpbh.nv.gov
Email: ehscustomerservice@health.nv.gov

Attachment H

VENABLE LLP

600 MASSACHUSETTS AVE., NW WASHINGTON, DC 20001
T 202.344.4000 F 202.344.8300 www.Venable.com

Todd A Harrison
T 202.344.4724
F 202.344.8300
taharrison@venable.com

February 21, 2023

Via FedEx
And Email: *bejohnson@washoecounty.gov*

Ms. Briana Johnson
Environmental Health Specialist
Washoe County Health Department
1001 E. Ninth Street
Reno, NV 89512

Re: Cava Kava LLC's Kava Bar

Dear Ms. Johnson:

We write on behalf of our client, Cava Kava LLC's, proposed new Kava bar which will be located at 935 N. Virginia Street, Reno, Nevada 89503. It is our understanding the County is refusing to permit our client's new establishment from serving Kava tea to its customers. It is our further understanding that the County's basis for refusing this request is that Kava is not an FDA-approved food additive, nor otherwise considered generally recognized as safe ("GRAS"). The County further indicated to our client that Kava may only be marketed as a dietary supplement and, without citing any authority, indicates that dietary supplements cannot be served to customers who visit the Kava bar. However, it is unclear how the County comes to this conclusion given that the law directly contradicts this position. Predictably, the County fundamentally misunderstands and misstates the applicable law. In this regard, Kava, when used in its traditional preparation as a tea, is not a food additive but the food itself. This is a distinction with a significant difference in regulatory categorization.

More specifically, there are three categories of food: (1) the food itself; (2) food additives; and (3) dietary supplements. Importantly, food itself is not subject to the food additive provision of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act" or the "Act"). Only when a food is an ingredient in a multicomponent food product does it implicate the food additive provisions of the Act. Failure to understand this distinction leads to misapplication of the food additive provisions to the food itself. Indeed, it appears the County failed to understand the critical distinction between a food and a food additive under the FD&C Act. Specifically, the Act defines "food" as "articles used for food or drink for man or other animals." *See* FD&C Act § 201(f)(1). In contrast, a food additive is defined as a substance that is added to a food that is not otherwise GRAS or a dietary ingredient. *See* FD&C Act § 201(s). The difference between a food and food additive is simple, the former does not require an approval under the FD&C Act while the latter does require approval unless it is GRAS or a dietary ingredient. For instance, coffee and tea are

food, not a food additive. Similarly, ginseng tea can either be a food or dietary supplement but is not a food additive nor does FDA consider it GRAS. Yet, it permits the marketing of ginseng tea because it's a food, not a food additive. Similarly, dried Kava root is routinely sold and consumed as food and steeping it in water does not transform it into a food additive. Indeed, Pacific Islanders worked with the World Health Organization, the UN, and Food and Agriculture Organization to get each region's cultivars of Kava, including Kava produced in Hawaii, added to the *Codex Alimentarius* International Safe Foods Standards as a beverage. Importantly, neither the FDA nor the USDA objected to this listing, and tacitly agreed with the safety assessment. Thus, it rings hollow that the County now objects to its use as a food on the grounds that it is not an FDA-approved food additive that is GRAS. Indeed, as noted, the FDA agreed with the assessment of *Codex* that Kava is a food/beverage, and it did not raise any concerns over its safety.

From a legal perspective, the argument that steeping Kava root in water transforms the Kava into a food additive subject to GRAS law is without merit and contrary to the case law, which the County apparently failed to take into consideration. Indeed, when courts have looked at this distinction in other but similar contexts, the courts have ruled that it strains credulity to find that a food is a food additive when the other ingredients in the product are merely the vehicle for consumption. This point is illustrated by *United States v. 29 Cartons of Black Currant Oil, An Article of Food,* 987 F.2d 33 (1st Cir. 1993) and *United States v. Two Plastic Drums, More or Less of Food Labeled Black Currant Oil*, 984 F.2d 814 (7th Cir. 1993) reh'g denied, 1993 U.S. App. LEXIS 6742 (7th Cir. Mar. 31, 1993). Both cases involved multi-ingredient foods that consisted of their main component of black currant oil ("BCO"), which was to be encapsulated in glycerin and gelatin. The GRAS status of the latter two ingredients was not in dispute. Rather, the issue presented to both courts is whether BCO is an unapproved food additive. The FDA argued that the BCO was a food additive because it was being added to the finished capsule and, thus, was an unapproved food additive that the agency did not believe was GRAS. In essence, the FDA was arguing that the GRAS ingredients was the food and BCO was the additive. Both courts rejected the FDA's spurious argument, as the purpose of the capsule was to simply provide a delivery method for the oil. Specifically, the courts found that adding BCO to the capsule did not cause it to lose its characteristics as a food. Rather, the courts found the capsule was only intended as a means of ingesting the BCO. As the First Circuit noted:

> "[t]he proposition that placing a single ingredient food product into an inert capsule as a convenient method of ingestion converts that food into a food additive perverts the statutory text, legislative intent, and defenestrates [throws out] common sense. We cannot accept such anfractuous reasoning."

Applying both courts' reasoning to Kava, steeping Kava root in water is simply a convenient and traditional method of ingesting the Kava (which nobody would deny that Pacific Islanders have a right to consume), as the water does not change the basic characteristic of the root and serves no purpose other than to provide a means to enjoy the Kava. Indeed, the FDA cannot restrict the selling of Kava as a tea as long as it is not combined with other herbs. To be clear,

Kava is the food, not an additive to water, as black currant oil was the food and not an additive to glycerin and gelatin. Kava root can be consumed as a dried root much like ginseng can be consumed as a dried root or as a tea. Importantly, Kava root steeped in water and consumed as a food is not subject to the food additive provisions of the FD&C Act. The case law is clear on this issue that when consumed as an herbal tea, Kava is a food and not a food additive. Accordingly, Kava tea is a food and may be safely consumed as either hot or cold tea, and the presence of water does not transform it into a food additive.

Even more peculiar is the suggestion that Kava tea, when marketed as a dietary supplement, cannot be served at a food establishment. Simply stated, there is not anything in the existing law, federal, or Nevada, that would prohibit our client from serving Kava tea as an herbal dietary supplement for consumption on its premises. Importantly, the FDA has never stated, nor could it, that dietary supplements cannot be consumed as teas; nor does it even have the authority to restrict the venues in which it may be sold. To make it clear, there is no legal authority the County can cite to that states it can restrict the sale of a dietary supplement and how it is consumed at any food establishment, including but not limited to a coffee house, smoothie bar, tea bar, or any other establishment that sells food. Indeed, as you are probably aware, many of these establishments specifically permit customers to add dietary ingredients to their beverages to give health-conscious individuals another means of consuming their dietary supplements. All you need to do is go into your local Jamba Juice or health club. We seriously doubt that the County plans to act against every establishment that permits consumption of dietary ingredients on its premises, including smoothie bars and health clubs, and to specifically single out Kava teas smacks of discrimination against a traditional Pacific Islander beverage, and would be a clear case of arbitrary and capricious behavior on the County's part. In the end analysis, there is simply no federal or state law or regulation that prohibits this practice of marketing Kava tea as either a food or dietary supplement. At worst, it discriminates against the traditional beverage of Pacific Islanders while permitting Jamba Juice to flaunt the proposed laws with more Eurocentric herbal ingredients.

Finally, this action by the County is costing our client considerable damages. This baseless decision has significantly impacted the Company's to be competitive in the local marketplace, while smoothie establishments, health clubs, and coffees shops routinely add dietary supplements to their offerings. Moreover, our client's reputation and credibility within the community has been significantly tarnished by this unjustified action, and those damages continue to mount every day. Our client prefers to resolve this matter amicably; however, it is prepared to take all available legal action at its disposal to defend its rights to serve Kava tea at its establishment, whether as a traditional Pacific Islander beverage, or as a liquid dietary supplement being delivered in tea form. Neither act is prohibited under the FD&C Act nor Nevada law, and the County cannot cite to any ordinance, regulation, or statute to the contrary. Accordingly, we respectfully request that the County formally inform our client that it may serve Kava tea to its customers.

* * *

We trust this letter provides you with a sound basis to permit our client to sell Kava tea at its new establishment. Please let us know if you have any questions or would like to set up a time to discuss this matter.

Best regards,

Todd A. Harrison
Counsel to Cava Kava LLC

Attachment I

WASHOE COUNTY HEALTH DISTRICT
ENHANCING QUALITY OF LIFE

WASHOE COUNTY HEALTH DISTRICT
ENVIRONMENTAL HEALTH SERVICES DIVISION
1001 East Ninth Street, Building B, Reno, Nevada 89512
Telephone (775) 328-2434 • Fax (775) 328-6176
www.washoecounty.us/health
healthehs@washoecounty.us

FACILITY CONSTRUCTION INSPECTION REPORT

Inspection Type: Opening Reinspection w/o Fee

Inspection: Final

DBA/Name:	Type:	Date:	Time In/Out:
RENO ROOTS	Snack Bar	2023-02-27	13:00:00 14:10:00

Address:	City/Zip:	WBLD Permit #:
935 N VIRGINIA ST A, RENO, NV 89503	RENO 89503	BLD23-0563E

Person in Charge:	WCHD Permit #:
Neil Cavanagh	H23-0087FOOD

Observations and Corrective Actions:

-All construction has been signed off at this time.
-Facility has a storage room to the west of the main bar area.
-Backflow device: Zurn 975XL2 is present in the Insomnia Cookie storage room in the basement. Passing backflow test results from 2/16/2023 provided.
-Operator has a storage room downstairs for miscellaneous items. This space may not be used to store any food products or single service items unless it is properly finished to be smooth and easily cleanable and non-absorbent.
-Restrooms are available in the facility.
-This is a risk category 1 snackbar.
-Hours: 12 pm - 8 pm.
-Facility is not completing any special processes requiring an Operational or HACCP Plan at this time.
-Discussed proper handwashing with operator.
-Discussed public vomiting and diarrheal incidents. Facility must have a written SOP on-site.
-Facility must ensure that ill employees with vomiting, diarrhea, sore throat w/ fever, and/or jaundice are excluded for an extra 24 hours after the last symptom has stopped.
-Discussed requirement for kitchen staff to wear hats or hairnets and a beard net (if applicable).
-Discussed the 9 major food allergens and that facility person-in-charge must be knowledgeable about the 9 major food allergens: dairy, egg, soy, wheat, peanuts, tree nuts, sesame, shellfish, and fish.
-Facility is using chlorine sanitizer and has appropriate test strips available.
-Discussed calibration of the food thermometer with no issues noted.
-All cold holding units observed at 41F or less.
-Facility will be washing lemons and limes to cut for beverages. Operator does not have a prep sink, so fruit may be washed in the 3-compartment sink so long as the sink is washed, rinsed and sanitized before and after.

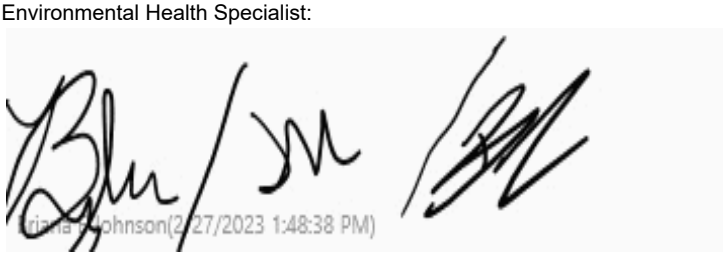
Observations and Corrective Actions Cont'd:

-Discussed that Washoe County Health District (WCHD) will be undergoing a name change and will be known as Northern Nevada Public Health in the near future.
-At the time of this opening inspection, the facility is only approved to prepare and sell tea, dairy, fruit, water, sodas, and energy drinks. The facility is not approved to sell any products that include kava, kratom, or CBD. If the operator would like to sell pre-packaged kava, kratom, or CBD within their facility, they must provide documentation showing that the product is coming from an approved source per the FDA. This documentation must be reviewed for approval by WCHD.
-Any supplement that is not on the FDA Generally Recognized As Safe (GRAS) list cannot be used in foods or beverages as an ingredient. Kava and any other supplement can only be manufactured, processed, packaged, and/or labeled as a supplement in a facility that is under FDA or other State/Local regulatory oversight. The Nevada Department of Health and Human Services is the agency with regulatory oversight of supplements in Washoe County – they can be contacted for additional information regarding the use of supplements.
-Please be advised that supplements not on the GRAS list are limited to personal use and shall be obtained from suppliers in hermetically sealed individual packages and sold to customers as is.

-This inspection report will act as your permit to operate.

***Okay to Operate!

Failure to abate violation required in this notice may result in immediate suspension of the Permit to Operate. An opportunity for an appeal will be provided if a written request for a hearing is filed within the period of time established in this notice for the correction of violations. (Reference: NRS 446.895)

Environmental Health Specialist: 	Received By: 

Attachment J

From: English, Amber E.
To: nelcavanagh1@yahoo.com
Cc: Johnson, Briana; Collins, Byron; Reid, Dania
Subject: Reno Roots - Response to Cava Kava LLC"s Kava Bar Letter 2-21-23
Date: Friday, March 31, 2023 8:44:00 AM
Attachments: image001.png
image002.png
image003.png

Good morning, Mr. Cavanagh,

I am writing to inform you that after consideration and review of the objection letter we received from your attorney regarding adding Kava to beverages in your food establishment, the decision made by the Washoe County Health District (WCHD) at the time of your permit issuance will stand. Any substance that is not on the FDA Generally Recognized As Safe (GRAS) list cannot be used in foods or beverages as an ingredient. Pursuant to the Regulations of the Washoe County District Board of Health Governing Food Establishments, Section 010.275, water is considered food:

> **"Food" defined.** "Food" means any food, drink, confection or beverage, or any component in the preparation or manufacture thereof, intended for ultimate human consumption, stored, being prepared or manufactured, displayed, offered for sale, sold, or served in a food establishment or temporary food establishment (NRS 446.017).
>
> For the purpose of these regulations, water and ice served or offered in a food establishment, and chewing gum, are considered food.

Kava (Piper methysticum) is not an approved additive and adding this substance to any food or beverage is a violation of the Regulations of the Washoe County District Board of Health Governing Food Establishments:

> **§ 010.280 "Food additive" defined.** "Food additive" means any substance, the intended use of which results directly or indirectly, in it's becoming a component or otherwise affecting the characteristics of food.
>
> A. "Food additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(s) and 21 CFR 170.3(e)(1).
>
> B. "Color additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR 70.3(f).
>
> **§ 050.050 Additives**
>
> Food may not contain unapproved food additives or additives that exceed amounts specified in *21 CFR 170-180* relating to food additives, generally recognized as safe or prior sanctioned substances that exceed amounts specified in *21 CFR 181-186*,

substances that exceed amounts specified in *9 CFR Subpart C Section 424.21(b) food ingredients and sources of radiation*, or pesticide residues that exceed provisions specified in *40 CFR 180 Tolerances for pesticides chemicals in food, and exceptions*.

Kava and any other supplement can only be manufactured, processed, packaged, and/or labeled as a supplement in a facility that is under FDA or other State/Local regulatory oversight. The Nevada Department of Health and Human Services is the agency with regulatory oversight of supplements in Washoe County – they can be contacted for additional information regarding the use of supplements. Please be advised that supplements not on the GRAS list are limited to personal use and shall be obtained from suppliers in hermetically sealed individual packages and sold to customers as is.

We appreciate and respect the challenges of operating a food establishment. It is imperative that you recognize our responsibility as well as yours for protecting public health in our community. It is also important for you to recognize our intent to ensure that all permitted food establishments in our jurisdiction are being held to the same standards and requirements. As we discussed during our initial meeting, if you are aware of any other food establishments permitted by the WCHD that are currently serving the above referenced product, please submit that information to this office so we can investigate.

We understand that you may not agree with this decision and may have additional questions or concerns. However, we ask that you respect the decision and work with us to move forward.

Regards,

Amber English, REHS
Environmental Health Specialist Supervisor| Environmental Health Services Division | Washoe County Health District
aeenglish@washoecounty.gov | (775) 433-4015| 1001 E. Ninth St., Bldg. B, Reno, NV 89512

WASHOE COUNTY HEALTH DISTRICT
ENHANCING QUALITY OF LIFE
Public Health

[WashoeEats.com]WashoeEats.com

Attachment K

Post-market Determinations that the Use of a Substance is not GRAS

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, any substance used or intended for use in food must be authorized by FDA for use as a food additive unless the use of that substance is generally recognized as safe (GRAS) by qualified experts or meets a listed exception to the food additive definition in the Act (sections 201(s) and 409 of the FD&C Act; 21 U.S.C. 321(s) and 348). The use or intended use of a food additive that does not conform with an authorizing regulation (or effective food contact notification, if applicable) is an unapproved food additive and is deemed to be unsafe. Food that is or bears or contains a food additive that is unsafe is adulterated (section 402(a)(2)(C) of the FD&C Act; 21 U.S.C. 342(a)(2)(C)).

As part of its on-going compliance activities, FDA identifies foods that contain a substance for which there is no authorization as a food additive and then reviews the regulatory status of this substance. FDA scientists analyze whether there is a basis to conclude that the intended use of the substance is GRAS or meets a listed exception to the food additive definition. When FDA scientists determine that a substance is an unapproved food additive because it is not GRAS for its intended use (and does not meet a listed exception), they may document their findings in a memo.

These memos are available below, as well as links to FDA actions associated with these substances and other communications. These memos are specific to whether the use of a substance in food is an unapproved food additive. The use of such a substance may result in other violations of the FD&C Act. These other violations of the FD&C Act may be referenced in the links to activities related to that substance but are not addressed in these memos. This inventory is not a complete list of substances for which the intended use in food is not GRAS and may not include all actions the agency has taken with respect to unapproved food additives or a particular substance. This may not include memos related to ongoing investigations.

The inventory of these determinations provides the following information:

- Name of the substance
- Selection of known synonyms
- Chemical Abstracts Service (CAS) Registry Number®, if applicable

The substance name also serves as a hyperlink to the following additional information:

- Links to memos documenting FDA's determination that the use or intended use of the substance in food does not meet the statutory criteria for GRAS and is therefore an unapproved food additive
- Links to warning letters, enforcement actions, and other communications related to the substance

Search and display hints:

- Select the specific substance below to view additional details about any GRAS Notice.
- To sort by a specific field, click on the column header for that field.
- To browse the records, use the Show All, First/Previous/Next/Last, and Jump To options at the bottom of the data table.
- The search results will return hits of records containing words that include the search term. For example, a search for the color ***red*** will retur results that include terms such as *red*uce, ing*red*ient, and cultu*red*. To limit results to only the searched term, place a space before and after the word in the basic search or in the advanced search "this exact phrase" field.

Download data[5] from this searchable database in Excel format. If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players[6].

Basic Search | **Advanced Search** | **Field Search**

Search: Show Items Clear

Records Found: 12 **Page 1 of**

CAS Reg. No.*	Substance*	Other names
63-05-8	4-androstenedione	♦ androstenedione ♦ A4 ♦ androst-4-ene-3,17-dione
1420-49-1	Arimistane	♦ androsta-3,5-diene-7,17-dione
—	Betel nut	♦ areca nut ♦ Areca catechu seed
—	Caffeinated alcoholic beverages	
13956-29-1	Cannabidiol (CBD)	♦ cannabidiol
5957-75-5	Delta-8-THC	♦ delta-8-tetrahydrocannabinol
105-41-9	1,3-DMAA	♦ 1,3-dimethylamylamine ♦ 1,3-dimethylpentylamine ♦ 2-amino-4-methylhexane ♦ 4-methyl-2-hexanamine ♦ 4-methyl-2-hexylamine ♦ dimethylamylamine ♦ DMAA ♦ Forthane ♦ Geranamine ♦ methylhexanamine ♦ methylhexanenamine ♦ 2-hexanamine, 4-methyl- ♦ pentylamine, 1,3-dimethyl-
2395737-08-1	*Ginkgo biloba*	♦ Ginkgo ♦ maidenhair tree
—	Kava	♦ Piper methysticum ♦ kava kava
73-31-4	Melatonin	♦ melatonine ♦ N-acetyl-5-methoxytryptamine

CAS Reg. No.*	Substance*	Other names
—	Partially Hydrogenated Oils	♦ PHOs
62936-56-5	Picamilon	♦ picamilon sodium ♦ 4-nicotinamidobutanoic acid ♦ pikamilon ♦ nicotinoyl-GABA

Definitions

- **CAS Reg. No.**: Chemical Abstract Service (CAS) Registry Number® for the substance, if available.
- **Substance**: Name of the unsafe food additive.

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/food/food-ingredients-packaging/food-ingredient-and-packaging-inventories
5. cfc/XMLService.cfc?method=downloadxls&set=Postmarket
6. http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/ViewingFiles/default.htm

Page Last Updated: 07/12/2023

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

Memorandum

Date: August 11, 2020

From: [redacted] Ph.D., Toxicologist
Division of Food Ingredients (DFI), HFS-255
Office of Food Additive Safety (OFAS)
Center for Food Safety and Applied Nutrition (CFSAN)

Through: [redacted], Ph.D., Branch Chief, DFI, OFAS, CFSAN

_____

Through: [redacted], Ph.D., Division Director, DFI, OFAS, CFSAN

_____

Subject: Review of the published literature pertaining to the safety of Kava for use in conventional foods

I. Introduction

This memorandum summarizes generally available information from the published literature and other informational sources on Kava (*Piper methysticum* G. Forster). The root is the part of the kava plant ordinarily used by consumers. The memorandum discusses kava root extract's chemistry, absorption, distribution, metabolism and excretion (ADME), and its potential mechanism(s) of action; and highlights concerns regarding its hepatotoxic and carcinogenic effects, and other adverse health effects associated with food uses of kava.

II. Literature Searches

The following primary literature databases were searched to retrieve scientific data published on kava: PubMed, ScienceDirect, Embase, ChemIDplus Advanced, Natural Medicines (formerly Natural Standard, and Natural Medicines Comprehensive Database), and Medline. The search terms used were kava, dietary intake of kava, ingestion of kava, kava hepatotoxicity, kava and anxiety, kava and CNS effects, adverse effects of kava, kava pharmacokinetics, metabolism of kava, human exposure of kava, and kava case reports. The entirety of the databases from

all the years available up to July 2020 was searched revealing more than 800 publications. In order to focus on literature most relevant to the use of kava as a "relaxation" beverage and/or as an ingredient in foods, the search was refined to identify studies related to the oral consumption of kava with greater emphasis on potential adverse effects in humans. The literature selected for this review describes some of the effects of kava on the liver, the central nervous system as well as other toxicities.

III. Background

Kava (*Piper methysticum* G. Forster), is a perennial shrub, a member of the pepper family Piperaceae, native to the geographic regions of Polynesia, Micronesia and Melanesia. Some of the common names for kava include intoxicating pepper, ava, ava pepper, awa, kava kava, kava pepper, kava root, kawa, kawa kawa, kew, rauschpfeffer, sakau, tonga, wurzelstock, and yagona.

Kava beverages have been used ceremonially and socially in the South Pacific for many centuries. Kava drinking was introduced to places like New Caledonia, the Solomon Islands, Kiribati, and New Zealand by migrants. Kava became popular in Western society as a recreational drink, a dietary supplement and used for medicinal purposes as an anxiolytic drug for anxiety and insomnia. Traditionally, kava extracts are prepared from macerated rhizome roots combined with cold water or coconut milk. Kava beverages made from fresh or dried roots of *Piper methysticum*, are consumed for their relaxant and psychoactive properties (Bilia et al. 2002). Commercially available kava formulations have been primarily ethanol, methanol or acetone extracts, standardized to specified kavalactone content.

Although there is some scientific evidence for the use of kava to treat anxiety, safety concerns over hepatotoxicity has resulted in withdrawal or ban in several European markets (France, Switzerland, Czech Republic, Spain, UK, Hungary, Portugal and Germany (up to 2015)) and Canada since 2002. FDA also issued a consumer advisory and a letter to health care professionals in 2002 expressing concern about liver damage in individuals who have ingested kava products (CFSAN, March 25, 2002). However, currently, kava is still available for sale in the U.S. as dietary supplements, promoted for relaxation to relieve stress, anxiety, and tension, as well as for sleeplessness and menopausal symptoms and in Australia and New Zealand as herbal medicine in the treatment of generalized anxiety.

In Australia, Kava has a Schedule 4 entry, and there is a regulatory limitation regarding the maximum of 250 mg kavalactones per day derived from water-based extracts of kava rhizomes and roots, with a limit per dosage of 125 mg kavalactones for any individual tablet or capsule (Therapeutic Goods Act (TGA), Oct. 2016).

The Committee on Herbal Medicinal Products (HMPC) of European Medicines Agency (EMA) concluded that based on the available data, a European Union

herbal monograph on kava cannot be established for the treatment of anxiety disorders (EMA Nov. 2017).

IV. Chemistry of Kava

Fresh kava rootstock has been reported to be comprised of about 80% water. Dried rootstock consists of about 43% starch, 20% fibers, 12% water, 3–4% proteins, 3% sugars, 3% minerals, and 3 to 20% kavalactones, depending on the age of the plant and the cultivar (He et al. 1997). More than 40 compounds have been isolated from kava, with the active components present in the lipid-soluble resin (Singh 2005).

There are three chemical classes in the kava resin:
(i) arylethylene-alpha pyrones;
(ii) chalcones and other flavanones; and
(iii) conjugated diene ketones.

The substituted 4-methoxy-5, 6-dihydro-alpha-pyrones or kava pyrones, commonly called kavalactones, possesses the highest purported pharmacological activities.

Kavalactones are concentrated mainly within the rhizomes, roots and root stems of the plant, with the highest concentration in the lateral roots, decreasing gradually towards the aerial plant structures. There are eighteen kavalactones that have been isolated and identified from kava root extract, six of which account for approximately 95–96% of the total kavalactones in the lipid resin, namely, kavain (K), 7, 8-dihydrokavain (DHK) methysticin (M), 7, 8-dihydromethysticin (DHM), yangonin (Y), and desmethoxyyangonin (DMY; 5,6-dehydrokavain) (Fu et al. 2008). In general, kavalactones have low water solubility (Côté et al. 2004). Minor constituents of kava extracts include amino acids, minerals (iron, magnesium, potassium, calcium, sodium and aluminium) and three chalcones (flavokavains A, B and C). Trace amounts of other compounds have been isolated such as alkaloids (pipermethystine, 3α, 4α-epoxy-5β-pipermethystine, and methoxy-cinnamoyl pyrolidine), flavonoids, ketones, phytosterols and aliphatic alcohols.

There are >200 kava varieties or cultivars categorized as noble cultivars, medicinal cultivars, “non-noble” or “two-day” (tudei) cultivars and wild (Wichmannii) species. Kava cultivars are established based on the chemical signature of the six kavalactones obtained from a kava sample. The chemotyping is based on the sequence of the elution of each kavalactone by HPLC and in their decreasing order of quantity. Table 1 shows the chemotype identity and reported “recreational” effects of the six main kavalactones. Hence, variations in chemical composition occur in different cultivars, plant parts, age of the plant, geographic and growth conditions (Singh et al. 2002).

Table 1:

Kavalactone	Chemotype	Reported Effects
Desmethoxyyangonin (DMY)	1	
Dihydrokavain (DHK)	2	Very sedating
Yangonin (Y)	3	
Kavain (K)	4	Euphoria or headiness
Dihydromethysticin (DHM)	5	Very sedating, long lasting
Methysticin (M)	6	

V. Biochemical Aspects of Kava

Absorption, Distribution, Metabolism, and Excretion (ADME)

Mice

Robinson et al. 2009 summarized the absorption of 6 kavalactones—K, DHK, M, DHM, Y, DMY, administered orally in a peanut oil solution to mice. Both K and DHK were rapidly absorbed from the gastrointestinal tract, the peak effect in mice being 10 minutes, as measured by a maximal electric shock test (no details provided about the test). M and DHM had a longer induction period, about 30 to 45 minutes, but also had a longer duration of action. Y and DMY were poorly absorbed from the gut peritoneum, and/or rapidly eliminated.

The pharmacokinetics of four kavalactones, K, DHK, Y, and DMY was studied in the mouse brain. Balb/c mice were administered intraperitoneally (i.p.) each of the kavalactones at a dose of 100 mg/kg, and were sacrificed at specific time intervals (5, 15, 30, and 45 min). The concentrations of these four compounds in brain was determined by GC/MS. After 5 min, DHK and K attained maximum concentrations of 64.7 and 29.3 ng/mg wet brain tissue, respectively, and were rapidly eliminated. In contrast, DMY and Y reached concentrations of 10.4 and 1.2 ng/mg wet brain tissue, respectively, and were more slowly eliminated from brain tissue. However, when crude kava resin (containing 44 mg/kg K and 18 mg/kg Y) was administered i.p. at a dose of 120 mg/kg, the brain concentrations of K and Y markedly increased (2 and 20 times, respectively) relative to the values measured from their individual injection. In contrast, DHK and DMY, after the administration of crude resin, remained similar to their levels obtained after individual i.p. injection suggesting a synergistic effect with kava resin compared with its individual constituents acting alone. The synergism in pharmacological activity appears to be due to potentiation of penetration into the brain when the compounds are administered together rather than separately. However, the mechanism by which this may occur remains unknown. Similarly, it has been reported that Y and DMY when given orally were relatively ineffective. But, in combination with other kava constituents, a marked increase in their potency was observed implying a synergistic action in the absorption of kavalactones from the intestine, when kava constituents are administered together rather than individually (Keledjian et al. 1988).

Rats

The oral pharmacokinetics of Kavain was studied in male Fischer 344 (F344) rats. Kavain (100 mg/kg) was administered either alone or with kava extract (256 mg/kg). The results revealed that K was well absorbed, with >90% of the dose excreted within 72 h, mainly in the urine. When K was co-administered with kava extract, the peak concentration of K (Cmax) in blood plasma was doubled and the area under the plasma drug concentration-time curve was tripled, demonstrating that the presence of other constituents had great impact on the ultimate pharmacokinetics of the whole herb. However, a 7-day pretreatment with kava extract had no effect on the pharmacokinetics of K administered on day 8 (Mathews et al. 2005).

The metabolism of 5 kavalactones (DHK, K, M, DHY and Y) was investigated in Wistar rats. Individual kavalactones were administered by stomach tube at a dose of 400 mg/kg (p.o). The results indicate that ~50% of the dose of DHK was found in the urine within 48 h mostly as hydroxylated metabolites, of which p-hydroxy-DHK was the most abundant and some hippuric acid (9-13% of the dose) was seen. With K, lower amounts of both hydroxylated and ring-opened urinary metabolites were found. M was poorly absorbed with very small amounts of only 2 metabolites seen. In the case of DHY and Y, relatively small amounts of urinary metabolites were formed via O-demethylation. DHK and DHY appear to be better absorbed than other compounds (Rasmussen et al. 1979).

Humans

Studies examining the metabolism of kava in humans are described below.

In vitro studies using Caco-2 cells found kavalactones to be potentially bioavailable as they all readily crossed the Caco-2 monolayers, most with more than 70% crossing within 90 min. There are two characteristics that appear to affect the permeability of the kavalactones. The first factor is the presence of the methoxy (OCH3) group at R2 and the absence of an oxygen functionality at R1. The second factor appears to be the other components present in the extract. The study suggests that the extraction method (aqueous or ethanolic) used is able to influence the total concentrations of kavalactones present in a preparation but does not markedly affect the bioavailability of these kavalactones (Matthias et al. 2007).

Duffield et al. (1989) identified human urinary metabolites of kavalactones following ingestion of aqueous kava extract prepared by the traditional method. Nine kavalactone metabolites were identified, including DHK, K, DMY, Y, tetrahydroxyangonin, 11-methoxytetrahydroyangonin, DHM, methylsticin, and dehydromethylsticin. Metabolites formed were due to the reduction of the 3, 4-double bond and /or demethylation of the 4-methoxyl group of the α-pyrone ring system. Demethylation of the 12-methoxy substituent in yangonin was also identified. In contrast to rats, no dihydroxylated or ring opened metabolites were detected. The main metabolic pathways for kavalactones in humans and rats are

hydroxylation of the C-12 in the aromatic ring, breaking and hydroxylation of the lactone ring with subsequent dehydration, reduction of the 7,8-double bond, and demethylation of the 4-methoxyl group.

Zou et al. (2005) analyzed urine samples of two human subjects (one male and one female Caucasian) after ingestion of 10 g of powdered kava root mixed in water. Analysis of the root extract showed that the total kavalactone content was 13%, which is in the typical range of the levels (3-20%) reported. 6-phenyl-3-hexen-2-one (6-PHO) was detected in the urine as a mercapturic adduct confirming the reactivity of 6-PHO with GSH observed in their *in vitro* studies. The authors suggest that 6-PHO could possibly conjugate with other nucleophiles such as protein thiols or DNA bases and potentially alkylate DNA or disrupt enzymatic and metabolic activity resulting in kava-associated hepatotoxicity.

Tarbah et al. 2003 investigated the metabolism of K in humans and found that *p*-hydroxykavain is the major metabolite that was found in blood and urine in its free and conjugate forms (glucuronide and sulfate). *p*-hydroxy-7,8-dihydrokavain was detected only in the urine. O-desmethyl-hydroxy-5,6-dehydrokavain and 5,6-dehydrokavain were the other K metabolites. After a single oral administration of kavain (800 mg), within 1 and 4 h after uptake, the serum concentrations ranged between 40 and 10 ng/ml for kavain, 300 and 125 ng/ml for p-hydroxykavain, 90 and 40 ng/ml for o-desmethyl-hydroxy-5,6-dehydrokavain, and 50 and 30 ng/ml for 5,6-dehydrokavain.

Toxicological studies

Acute toxicity

In an 8-day study, male Sprague-Dawley (SD) rats (6/group) received two different commercial kava products (kava A containing 80% or more kavalactones and kava B-unfiltered juice of the lateral roots) or vehicle by gavage. The results of the treatment with these products containing high doses of kavalactones (equivalent to approximately 380 mg kavalactones/kg/d; 100 times the suggested dose for humans) significantly increased liver weights, markedly enhanced the hepatic CYP1A1 mRNA expression (75-220 fold) as well as ethoxyresorufin O-deethylase (EROD) activities and CYP1A1 immunoreactivities. CYP1A2 mRNA expression was also moderately increased (2.8-7.3 fold) by both the kava products but to a much lesser extent than CYP1A1. The authors considered the NOAEL to be <380 mg/kg/day. The authors suggest that commercial kava products might exert their potencies to induce CYP1A1 in humans and its consequence may possibly be related to hepatotoxicity especially in susceptible individuals (Yamazaki et al. 2008).

A 2-week study was undertaken to mimic a short-term interaction between heavy kavalactones (KL) dosage and incidental consumption of kava alkaloid, pipermethystine (PM) in humans. The toxic effects of PM, abundant in leaves and stem peelings and acetone-water extracts (75:25, v/v) of kava rhizome (KRE) of

Hawaiian cultivar Mahakea were compared in F344 rats. PM and KRE were mixed in corn oil and administered via intragastric gavage daily for 2 weeks. The total content of KL in the acetone-water extract was 62.67%. This study KL dosage (63 mg/kg/day) was 10 times higher than the daily recommended dosage for human consumption (6–7 mg/kg/day) and may be comparable to mimicking the ‘‘heavy kava drinkers.’’ The results indicate that the treatment of F344 rats with PM (10 mg/kg) and KRE (100 mg/kg) for 2 weeks failed to elicit any significant changes in liver function tests or cause severe hepatic toxicity as measured by lipid peroxidation (malondialdehyde formation) and apoptosis markers (Bax, and Bcl-2 mRNA expression). Rats in all experimental groups lost overall body weight; however, KRE caused the most significant weight loss (42 g) compared with the control group. PM-treated rats demonstrated a significant increase in hepatic glutathione, cytosolic superoxide dismutase (Cu/Zn SOD), tumor necrosis factor α mRNA expression, and CYP 1A2, 2E1 and 2D6. The authors suggest that these effects reflect an adaptation to ROS-induced oxidative stress and possible drug-drug interactions. The lack of severe PM toxicity in rats may reflect possible differences in absorption, metabolism, and/or the variety of kava used. (Lim et al. 2007).

Singh and Devkota (2003) demonstrated that SD rats treated with aqueous kava extracts containing 200 or 500 mg KL/kg/d for 2 or 4 weeks did not exhibit any significant adverse effects in the liver function tests. Serum levels of any of the marker enzymes of liver toxicity such as alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase or lactate dehydrogenase were not elevated. There were no overt signs of clinical toxicity. Similarly, malondialdehyde (indicative of lipid peroxidation) levels in the liver homogenates did not increase suggesting a lack of liver toxicity by aqueous kava extract. The authors note that these kava doses were up to three times higher than the maximum recommended levels in humans.

Hepatotoxicity

The National Toxicology Program (NTP) conducted a comprehensive toxicology rodent study comprising a 2-week, 14-week (3 month), and 2-year toxicity and carcinogenicity studies in F344/N rats and B6C3F1 mice to address kava associated liver toxicity and carcinogenicity concerns. The study revealed clear evidence of carcinogenic activity in male mice with some evidence of carcinogenic activity in female mice, and an equivocal evidence of carcinogenic activity among male rats. In addition, kava extract caused increased incidences of tumor-like lesions in eyes, kidneys, liver, pancreas and forestomach in male and female rats, in the liver of male and female mice, and in the forestomach of female mice.

In the two-week studies, rats and mice were administered orally 0, 0.125, 0.25, 0.5, 1 and 2 g/kg/d kava extract by gavage. Kava-induced toxicity was observed in the livers of both rats and mice. Dose dependent increases in the absolute and relative liver weights were observed in the 1.0 g/kg and 2.0 g/kg males and in $\geq$0.5 g/kg in female rats. This was accompanied by significant increased incidences of minimal

hepatocellular hypertrophy (HP) in the 2.0 g/kg male and in 0.25 g/kg or greater female rats. In mice, liver weights were significantly increased in 2.0 g/kg males and females with accompanying increases in the incidence of hepatocellular hypertrophy in the 2.0 g/kg female mice. No other significant treatment-related effects were noted (Behl et al. 2011).

Subchronic study (NTP study)

Rats and Mice

In the 14-week NTP study, F344 rats and B6C3F1 mice (10/sex/group) were administered kava extract (30% kavalactones) in corn oil by gavage at doses 0, 0.125, 0.25, 0.5, 1.0, and 2.0 g/kg/d, 5 days per week, for 14 weeks. Exposure to kava extract resulted in unscheduled deaths of one female in the 1.0 g/kg group and three male and four female rats in the 2.0 g/kg groups. The authors attribute the cause of death to kava-induced central nervous system (CNS) and/or respiratory depression. Kava induced decreases in the body weights in the high dose groups in both sexes. Clinical chemistry analyses indicated increases in the activities of γ-glutamyl-transpeptidase (GGT) in the 1.0 g/kg females and both sexes of 2.0 g/kg group. Increased serum cholesterol levels were found in 0.5 g/kg and higher dose groups of both sexes. Dose-related increases in the absolute and relative liver weights and the incidence and severity of HP observed in males at 1.0 g/kg and females at 0.5 g/kg and higher were considered to be adaptive in nature by the authors. Immunohistochemical analyses of the protein expression of CYP enzymes in livers of these same rats showed an increased expression of CYP 1A2, 2B1, and 3A1 in both sexes from the 1.0 and 2.0 g/kg dose groups and decreased expression of CYP 2D1 (human 2D6 homolog) in female rats in the 2.0 g/kg group. Based on the neurotoxic and hepatotoxic effects, the authors considered NOAEL to be 0.25 g/kg in both sexes (Clayton et al. 2007). In mice, deaths of four male and three female 2.0 g/kg mice died during week 1 were attributed to kava extract. The mean body weights of the kava-treated groups were not significantly different from the controls. Ataxia and lethargy occurred in males and females of highest dose groups during week 1. The liver weights of 2.0 g/kg males and 1.0 and 2.0 g/kg females were significantly increased compared to those of the control groups. The incidences of centrilobular hypertrophy in the liver of 0.5 g/kg or greater males and 1.0 and 2.0 g/kg females were significantly greater than those in the vehicle controls.

Guo et al. (2009, 2010) analyzed the whole gene expression changes in the livers of male F344 rats and male B6C3F1 mice administered five different doses (0, 0.125, 0.25, 0.5, 1.0, 2.0 g/kg/d) of kava extract (30% kavalactones) in corn oil by gavage, 5 days per week, for 14 weeks. Microarray analyses of the changes in gene expression were also validated by real-time PCR. In rats, in the high dose group (2.0 g/kg), 72 drug metabolizing enzyme associated genes were significantly altered including 19 Phase I metabolizing enzymes genes; 21 Phase II genes; and 32 transporters (Phase III). In all the three higher dose groups, 7 Cyp genes were altered in a dose-dependent manner. While gene expression of Cyp1a1, 1a2, 2c6,

3a1, and 3a3 increased; Cyp 2c23 and 2c40 decreased. The authors point out that Cyp1a1 is primarily expressed in extrahepatic tissues and there is a low amount in the liver. The Cyp1a1 isozyme can metabolize a number of xenobiotics, including those with flat and planar structures, which include the highly toxic and tumorigenic polycyclic aromatic hydrocarbons (PAH). Therefore, the authors suggest that kava induced Cyp 1a1 may enhance the metabolism of PAHs and adversely affect human health.

In mice, in the high dose treatment group, there were some early deaths in the first week of treatment. Mean body weights were about 6% lower and the absolute and relative liver weights were significantly increased when compared to the controls. Gene expression profiles from the livers revealed that there were 95 drug metabolizing enzyme associated genes significantly altered including 28 Phase I metabolizing enzymes genes; 29 Phase II genes; and 38 transporters (Phase III). The expression of 5 genes (Gsta1, Gsta2, Cyp2a5, Cyp2b20, and Cyp2c55) increased in a dose-dependent manner. Significant changes were observed in the gene expression of Cyp 1a1, Cyp1a2, and Cyp3a11. Further, the most prominent changes were observed in the highest dose group, in the genes involved in the detoxification process, with Gsta1, Gsta2 and Nqo1 genes increased by about 50-, 24- and 4-fold, respectively. The authors speculate the enhanced expression to Nrf2 activation, since these genes are target genes controlled by transcription factor, Nrf2. Histopathology results in the male mice administered 0.5 g/kg and higher dosages of kava extract showed minimal to moderate hepatocellular centrilobular hypertrophy (increased severity with increasing dose). Interestingly, no other severe liver toxicities were observed. Based on the gene expression changes in both rats and mice, the authors suggest that kava extract can significantly modulate drug metabolizing enzymes, potentially leading to herb-drug interactions and hepatotoxicity.

Interestingly, in a study investigating the toxicity of an ethanolic kava extract (7.3 or 73 mg/kg/day) in Wistar rats for 3 or 6 months, no signs of toxicity were found, based on changes in body weight, hematological and liver parameters, and macroscopic and microscopic histological changes in the major organs. Although, the authors concluded that their results do not support kava induced liver toxicity, it should be noted that the doses used are significantly lower than those used in NTP study (Sorrentino et al., 2006).

Dog studies

Mongrel dogs received oral exposure to kavain at doses 10-400 mg/kg daily for 3 months. The results revealed the presence of mild toxicity in high dose group dogs and proliferation of small cells of the thyroid epithelium and a multicentric liver necrosis in one dog in high dose group (Hapke et al., 1971).

Chronic toxicity study (NTP study)

In the 2-year toxicity and carcinogenicity studies (Behl et al., 2011), F344 rats and B6C3F1 mice (50/sex/group) were administered kava extract in corn oil by gavage, at concentrations of 0, 0.1, 0.3, 1.0 g/kg (rats) and 0, 0.25, 0.5, 1.0 g/kg (mice), respectively. Chronic administration of kava in rats did not significantly affect survival or body weight in either males or females. In mice, the survival was not affected in either of the sexes. However, there was a slight reduction in the body weight gain in the female mice in the highest dose group. In rats, GGT activity increased several-fold at 18 months in males and at 6, 12, and 18 months in females. Bile salt concentrations were increased in both sexes. Cystic degeneration was observed in all dose groups of male rats. There were dose-related increases in the incidences of hepatocellular hypertrophy in rats and mice administered kava for up to 1 g/kg body weight. This was accompanied by significant increases in incidences of centrilobular fatty change. There were increased incidences of non-neoplastic lesions in the liver, forestomach, kidney, eye, and pancreas of male and female rats. In addition, a unique lesion was noted in the pancreas in the 1.0 g/kg males and females which included incidences of metaplasia of pancreatic acinar cells to a hepatocytic morphology. Microscopically, this lesion was characterized by the presence of small clusters of apparently normal hepatocytes adjacent to islets of Langerhans. The authors state that the etiology of this lesion remains unknown. There was no treatment-related increase in carcinogenic activity in the livers of male or female rats.

Male mice showed significant dose-related increases in the incidences and multiplicities of hepatoblastomas and hepatocellular adenomas as well as an increase in the combined incidences of hepatocellular carcinomas or hepatoblastomas indicating a **clear evidence** of carcinogenic activity in male mice. In female mice, there was a significant increase in the incidence of hepatocellular carcinomas and in the combined incidence of hepatocellular adenomas or carcinomas in the low and mid dose groups but not in the high dose group indicating **some evidence** of carcinogenic activity in female mice, accompanied by non-neoplastic lesions in the liver and forestomach. Based on these findings, NTP included this kava preparation into **group 2B**, meaning sufficient evidence in experimental animals.

In rats, although liver toxicity was observed, kava extract did not induce liver neoplasms suggesting species differences in the sensitivity of induction of liver neoplasms.

Retinal degeneration

In the 2-year NTP bioassay in F344/N rats, the frequency of retinal degeneration was significantly increased in a dose-dependent manner in the 0.3-g/kg and 1.0-g/kg groups in males, and in the 1.0-g/kg group in female rats, compared to the control groups. The proportion of bilateral change was significantly increased in the 1.0-g/kg group compared to the control group in both males and females. In the evaluation of peripheral retinal degeneration, the average severity grade was significantly increased in a dose-dependent manner in the 0.3-g/kg and 1.0-g/kg

groups in males, and in the 1.0-g/kg group in females, compared to the control groups. The degeneration consisted of a thinning and loss of the external retinal layers, such as the photoreceptors and external nuclear layers, with a decreased cellularity and disorganization of the remaining retinal layers. Reduced photoreceptor outer segment disc shedding and subsequent lower number of phagosomes in the retinal pigment epithelium and alterations in the melatonin pathway may have contributed to the increased incidences of retinal degeneration (Yamashita et al. 2016; 2018).

Effect of kava on CYP 450 enzymes

***In vitro* studies**

Rats

Rat hepatocytes treated with the six kavalactones, showed that only DHM and DMY markedly induced CYP3A23 expression (~7-fold) accompanied by increased levels of CYP3A23 mRNA. Interestingly, six kavalactones, mixed at a non-inductive concentration (15 µM for each), caused induction similar to 90 µM DHM or DMY. However, selective removal of both DHM and DMY, completely abolished the inductive activity of the mixtures suggesting that the induction is additively/synergistically enhanced by other kavalactones. DHM and DMY only slightly activated rat and human pregnane X receptor (PXR). The authors suggest that the induction of CYP3A23 by these 2 kavalactones involves transcription activation through a PXR-independent or PXR-involved indirect mechanism (Ma 2004).

The *in vitro* studies suggest that kava supplementation may give rise to significant CYP-mediated herb-drug interactions.

Humans

Côté et al. (2004) compared the kavalactone composition of the traditional aqueous kava root extract (Moi variety), organic kava extracts (acetone, ethanol or methanol) and extracts from commercial caplets which revealed significant differences in the total amount of kavalactones (2-3 fold) and the ratio of the six major KL. The ratio of the 6 major KL was significantly different in aqueous extracts with very low concentration of yangonin whereas the organic extracts were almost identical to one another. The commercial caplets were high in kavain and dihydrokavain. The aqueous kava root extract contains the lowest proportion of KL of all the root extracts, as expected from the reported low water solubility of KL. All the extracts (aqueous, acetone extract and caplet extract) inhibited the activity of the human liver microsomal P450 enzymes, CYPs 1A2, 2C9, 2C19, and 3A4, with the aqueous extract being the least potent. The authors suggest that the variations in the health effects reported for the kava extracts may be due to the differences in the proportion of KL and use of different preparation protocols.

The effect of kava extract and its constituents on human P450 enzyme activity was investigated *in vitro* using human liver microsomes. When hepatic microsomes were incubated with whole kava organic extract (normalized to 100 µM kavalactones), the activities of CYP2C9, CYP2C19, and CYP3A4 were most markedly inhibited (78 to 92%) compared to the control. There were also significant decreases in the activities of CYP1A2 (56%), CYP2D6 (73%), and CYP4A9/11 (65%). In the case of individual kavalactones at a concentration of 10 µM, M, and DHM, were most potent inhibitors followed by DMY. K did not inhibit these enzymes. DHM strongly inhibited CYPs 2C9, 2C19 and 3A4 (54-76%), M inhibited 2C9, 2D6 and 3A4 (27-58%) and DMY inhibited 2C9 and 3A4 (40-42%) (Mathews et al. 2002). *K*i values for the inhibition of CYP2C9 and CYP2C19 activities by M, DHM, and DMY ranged from 5 to 9 µM. K and DMY (<9 µM) modestly stimulated human P-glycoprotein ATPase activities (Mathews 2005).

In another *in vitro* study (Zou et al. 2004) using both cDNA-expressed human enzymes and cryopreserved human hepatocytes, ethanolic extract of dried kava root and three purified kava lactones (M, DMY, and Y) were found to be potent inhibitors of CYPs 1A2, 2C9, 2C19, 2E1, and 3A4 with IC_{50} values <10 µM. The individual KL were also moderately cytotoxic to human hepatocytes (EC_{50} values of approximately 50 µM). Methysticin was the most potent CYP enzyme inhibitor and most cytotoxic affecting hepatocyte viability followed by kava root extract, DMY and Y. These results suggest that kava could potentially reduce the metabolic clearance of a number of co-administered drugs. Moreover, the CYP2C9 and 2C19 being polymorphic, the effects could vary among genetically different individuals.

In vitro studies in human hepatocytes (HepG2) examining the hepatotoxicity of kavain, methysticin and yangonin demonstrated that kavain had minimal cytotoxicity, methysticin showed moderate concentration-dependent toxicity and yangonin (25 µM) displayed marked toxicity with ~ 40% reduction in cell viability unlike it's least toxicity in cryopreserved hepatocytes (Zou et al. 2004). Apoptosis was induced by yangonin and methysticin indicating that the predominant mode of cell death was apoptosis rather than necrosis. No significant changes were observed in glutathione levels suggesting that glutathione depletion may not be involved in the kavalactone induced injury (Tang et al., 2011). The authors note that the discrepancy in yangonin toxicity may be due to the use of cultured hepatocytes versus cryopreserved hepatocytes.

The above *in vitro* studies using cDNA–expressed CYPs, human liver microsomes, or cryopreserved or cultured hepatocytes, kava extracts and specific kavalactones have been shown to inhibit a variety of human CYP isoforms in the low micromolar range.

***In vivo* studies**

Russmann et al. (2005) conducted a small study in 6 healthy volunteers from New Caledonia, who were regular consumers (>6 years) of the traditional aqueous kava

extract (7-27 g kavalactones/week) up to the beginning of the study who agreed to abstain from kava for 30 days. Determination of metabolic ratios after oral administration of 5 probe drugs reflecting CYP enzyme activity during kava drinking and after a 30-day kava abstinence demonstrated the inhibition of CYP 1A2. However, this practice had no effect on the phenotypic markers of CYP2C19, 2D6, 2E1, or 3A4 function.

In contrast, Gurley et al. (2005) observed that 30 days of kava supplementation in healthy volunteers had no effect on the phenotypic markers of CYP1A2, CYP2D6, or CYP3A4 activity; but CYP2E1 activity was significantly inhibited (~40%).

M, DHM, and DMY appear to be the most potent inhibitors of CYP3A4. Inhibition of 3A4 could lead to elevated plasma levels of simultaneously ingested drugs with potential liver toxicity.

Mechanisms of toxicity

Many mechanisms have been postulated to explain the unexpected toxicity, one being pharmacokinetic interactions between kavalactones and co-administered drugs involving cytochrome P450 enzyme system. Alcohol is often co-ingested in kava hepatotoxicity cases.

It has been reported that 7-9% of Caucasians (Poolsup et al., 2000) 5.5% of Western European, almost 1% of Asian are homozygous deficient in CYP2D6, while it is almost 0% in persons of pure Polynesian descent (Wanwimolruk et al., 1998). Similarly, CYP 2C19 (wild type) gene is absent in 2 to 6% of Caucasian populations and in up to 20% of Asian populations (Zou et al 2004). Thus, genetic polymorphism of CYP enzymes may be one of the factors contributing to the differences in the hepatotoxic response between Pacific islanders and Caucasians.

Overall, it can be concluded that these findings indicate that kava has a high potential for causing drug interactions through inhibition of P450 enzymes responsible for the majority of the metabolism of pharmaceutical agents.

Neurological effects:

The major physiological action in humans is consistently reported as a pleasant, mild, centrally acting relaxant property which induces a generalized muscle relaxation and, ultimately, a deep natural sleep. A minor property of kava is its local anesthetic properties which are experienced as numbing of the mucous membranes of the mouth and tongue when the beverage is consumed.

K and DHK are reported to exert the strongest anxiolytic activity. The psychotropic effects of kava are achieved by the modulation of gamma-amino-butyric acid (GABA) receptors. Although the exact mechanisms are not known, studies suggest that the effects are mediated via different mechanisms such as upregulation of GABA-A receptor function, blockade of voltage-gated sodium ion channels,

enhanced ligand binding across GABA-A receptor subtypes, and reduced excitatory neurotransmitter release.

Using an *in vitro* neonatal rat gastric-brainstem preparation, it was shown that kavalactones and DHK significantly inhibited the activity of the neurons in the nucleus tractus solitarius of the brain stem suggesting their role in the modulation of GABAergic neurotransmission (Yuan et al. 2002). Another *in vitro* study examining the functional effects of kavain at 9 different human GABA-A receptor subtypes expressed in xenopus oocytes found that kavain positively modulated all receptors regardless of the subunit composition, but the degree of enhancement varied at certain receptors. Thus, providing evidence for the direct interaction of K with GABA-A receptors. The modulatory effect of kavain was unaffected by flumazenil, indicating that kavain did not enhance GABA-A receptors via the classical benzodiazepine binding site. It is interesting that K and diazepam did not modulate GABA-A receptors in an additive manner (Chua et al. 2016).

Thus, N-methyl-D-aspartate (NMDA) receptors and/or voltage-dependent calcium channels may be also involved in the elementary mechanism of action. Their effect on the brain is different from that of benzodiazepines or tricyclic antidepressants. The anticonvulsive properties are similar to those of local anesthetics, especially procaine. Analgesia produced by kava occurs via non-opiate pathways.

In addition, a synergistic effect is possible for substances acting on the central nervous system, such as alcohol, barbiturates and psychopharmacological agents.

Effects of Alcohol

Kava is often consumed with alcohol, which may potentiate the hepatic injury. Jamieson and Duffield observed the positive interaction of intraperitoneally administered ethanol and orally administered kava resin in male Balb/c mice. The authors stated that kava resin significantly increased alcohol hypnosis and noted that 300 mg/kg kava resin proved to be lethal to 3 of 6 mice treated with 4 g/kg ethanol, indicating that toxicity and hypnosis were increased. (Jamieson and Duffield, 1990).

Genotoxicity test

The mutagenicity of 6 major kavalactones as well as different solvents kava extractions of roots, leaves, and stem peelings were evaluated using the *umu* test (a sensitive test for point mutations). The results indicated that the 6 KL (100-300uM) were not mutagenic. Two C-glycoside flavonoids (2''-O-rhamnosylvitexin and schaftoside) isolated from *n*-butanol fraction of kava leaves displayed mutagenic potential (Jhoo et al. 2007). Bacterial mutagenicity and *in vivo* micronucleus studies also indicate that kava extract is not mutagenic (Whittaker et al. 2008).

VI. Safety Concerns of the Use of kava in Food

Although small doses of kava induce muscle relaxation and/or drowsiness, long-term and excessive use of kava can lead to malnutrition, weight loss, and apathy**.**

Adverse effects of kava consumption

Hepatotoxicity

Case reports

Kava associated hepatotoxicity is the most concerning adverse effect and has led to bans in Germany, Switzerland, France and Canada. Several cases of liver damage have been associated with kava exposure in Europe including hepatitis (Humberston et al., 2003; Stickel et al., 2003), cirrhosis and liver failure (Escher et al., 2001; Kraft et al., 2001), and death (Gow et al., 2003, Russmann 2001).

World Health Organization (WHO) identified and reviewed 93 case reports with presumed kava related hepatotoxicity. 79% cases involved women with an average age of 45 years using kava for anxiety. In this case series, 7 patients died and 14 had liver transplants. 8 cases with probable associations (essential information for standard assessment available) and 53 cases with possible kava use and hepatotoxicity (insufficient data for a full assessment, or there were other potential causes of liver damage). 5 cases with a positive rechallenge. WHO conclusions after the review of these cases are 1. There is a significant concern of a cause and effect relationship between kava products and hepatotoxicity. 2. A nonrandom effect is indicated by a higher rate for the organic extracts than for synthetic products. 3. In organic extracts, components other than kavalactones might be responsible for hepatotoxicity. 4. Kava products have a strong propensity for kava-drug interactions. 5. Risk factors for hepatic reactions appear to be the use of organic extracts, excessive dose, heavy alcohol intake, pre-existing liver disease, and genetic polymorphisms of cytochrome P450 enzymes. Also, co-medication with other potentially hepatotoxic drugs and interacting drugs, particularly other anxiolytics, antipsychotics, and anti-thrombotics might lead to harm (Coulter et al., 2007).

26 cases of suspected kava hepatotoxicity reported from Germany (20) & Switzerland (6), of which 3 died, 6 survived after liver transplantation and the rest liver issues resolved after kava cessation & supportive care. Patients with hepatotoxicity all used ethanolic and acetonic extracts of kava. Teschke et al. (2008) re-analyzed and assessed the causality using the system of the Council for International Organizations of Medical Sciences, for probability scoring. The results of the analysis were as follows indicating that kava when taken as recommended carries a lower risk whereas overdose, prolonged treatment, and co-medication may carry an increased risk.

16-excluded due to lack of temporal association, independent of kava or co-medication
2-low score excluded
8-various degrees of causality

1- Toxic liver injury, probable causality for kava, the patient followed kava usage recommendations (≤120 mg/d kavalactones and ≤3 months)
1- Probable
1- Highly probable (rechallenge)
2- possible co-medicated drugs
3- possible overdose and/or longer duration

78 cases of hepatotoxicity have been reported following ingestion of commercial kava caplets. In several of these cases, hepatic failure required liver transplantation or has been fatal (Clouatre, 2004). Two cases have been attributed to depletion of human CYP2D6, the enzyme responsible for kavalactones metabolism (Anke, J., Ramzan, I. 2004). Most other cases involved concomitant ingestion of drugs known for their potential hepatotoxicity or of other pharmaceuticals, which suggests that herb–drug interactions may be implicated.

Becker et al. 2019 report first detailed case report of liver transplantation in a 45-year old female associated with kava use (100 mg daily) for 52 days in Brazil. The authors thoroughly investigated the case, analyzed the sample used by the patient to exclude contaminants and intrinsic toxicity of the substance. The chemical analysis demonstrated methanolic extraction and all the kavalactones were present with no contaminants or adulterants. Causality was inferred between liver damage & kava usage through the Roussel Uclaf Causality Assessment Method (RUCAM) algorithm.

Several studies show a clear association of increased level of liver enzymes GGT, ALP, and moderate to heavy kava beverage consumption as shown in Table 2.

Table 2

% population w/ Abnormal Liver function test results					
Study	Subjects	GGT	ALP	AST	ALT
Brown et al. 2007	Healthy Tongan (31+31)	65 vs. 26 control	23	Normal	Normal
Cairney et al. 2003	Australian Arboriginal (11)	73	65	NA	Normal
Clough et al. 2003	North Arnhem Aboriginal (98)	48	37	NA	24-29
Clough et al. 2003	East Arnhem Aboriginal (101)	61	50	NA	21-24
Russmann et al. 2003	New Caledonia (27)	85	NA	26-29	19-35
Mathews et al. 1988	Arboriginal	NA	NA	NA	NA

Hepatic injury due to traditional aqueous extracts of kava root was reported in a study of 27 heavy kava drinkers in New Caledonia (Russmann et al. 2003). Kava-induced toxic hepatitis was reported in a tourist after consumption of kava beverages (cumulative volume of 2-3L) in traditional Samoan Kava ceremonies (Christl SU et al. 2009). An outbreak of hepatitis A was associated with kava drinking in Western Australian Goldfields when a hepatitis A infected individual, a day after discharge from the hospital participated in kava drinking. The authors suggest that the source of hepatitis A infection was most likely during preparation of kava and/or via the shared drinking vessel (Parker et al. 2014).

In 2002, the US Centers for Disease Control and Prevention (CDC) issued a report on hepatotoxicity associated with kava-containing products. On March 25, 2002, the FDA warned that kava may be linked to serious liver damage, including hepatitis, cirrhosis, and at least four urgent liver transplants. FDA has issued warnings to consumers and physicians.

Phototoxicity

UVA irradiation of kava extract in the presence of a lipid, methyl linoleate, induced singlet oxygen and carbon-centered free radicals, which mediated lipid peroxidation, caused DNA strand cleavage, and generated 8-hydroxy-2′-deoxyguanosine (8-OHdG) adduct in human HaCaT skin keratinocytes. The results revealed that kava extract, 5,6-dehydrokawain, and yangonin are cytotoxic. The

authors of the study suggest that kava is photocytotoxic, photogenotoxic and human exposure to products that contain kava extract may enhance their sensitivity to skin dermopathy and skin cancer caused by ultraviolet A light or sunlight (Xia et al. 2012).

Dermopathy

Kava dermopathy is the most common side effect of excessive and chronic use of kava >310 g/week) and widely recognized in Fijians (Hannam et al. 2014). Kava dermopathy, a type of reversible icthyosiform dermatitis is presented as scaly skin rashes, urticaria, sebotropic eruption. It has been reported in approximately 45% of "regular" consumers, and up to 78% of heavy kava consumers (Rychetnic et al. 2011). Current and ex-kava users among Aboriginal population in northern Australia, showed a higher rate of kava dermopathy, lower body mass index, lowered blood lymphocytes and, in addition, current kava users showed elevated liver enzymes (Cairney et al. 2003). There are case reports of inflammatory sebotropic eruption with erythematous papules, pruritic eruptions on face and torso (Huynh et al 2014, Guro-Razuman et al. 1999). Recently, in the USA, inflammatory sebotropic eruption was reported in a female in her 30s who drank kava tea presented with notable facial swelling, postauricular lymphadenopathy and erythematous papules coalescing into plaques on the face, arms, thighs, chest, abdomen, and back. Her lab results showed significant elevation of white blood cell, eosinophil and neutrophil counts and liver enzymes (Brown-Joel et al. 2018). In UK, the first report of acute cutaneous toxicity in a 23-year old white woman to kava consumption showed inflammatory sebotropic eruption and urticaria with consistent clinical (pruritic, erythematous plaques with some facial swelling, fever and lymphadenopathy), histological (folliculocentric inflammation, rich in neutrophils lymphocytic) and biochemical (neutrophilia and transaminitis) features. (Steele et al. 2020). The sebotropic eruption is thought to be caused by the lipophilic nature of the kavalactones that accumulate in the lipids of the sebaceous glands which then leads to folliculocentric inflammation.

Allergy

Delayed hypersensitivity allergic skin reactions have been reported, including systemic/contact-type dermatitis, sebotropic reactions, and generalized erythema with papules following 2 – 3 weeks of use (Schmidt and Boehncke, 2000). Mast cells are key players in delayed hypersensitivity reactions. It is reported that when mast cells are exposed *in vitro* to aqueous extracts of kava prepared by traditional methods of Pacific islanders, highly active, unidentified components of the aqueous extract promoted calcium release, influx and the secretion of pro-inflammatory mediators which may be the causative components of kava-induced skin inflammation. Kavalactones (M, DHM and K) either alone or in combination did not elicit such response in mast cells (Shimoda et al. 2012).

Effect on Motor skills

In a population-based case-control study, the association between driving after consuming kava and serious injury-involved four-wheel motor vehicle crashes was conducted in Fiji. The results of the study showed that driving within 12 hr of consuming kava in recreational settings was associated with a four-fold increase in the odds of crash involvement, after controlling for confounding factors. Frequent use of kava over the previous 12 months (once a month to once a week and several times a week to daily) was also associated with increased odds of injury-involved crashes (Wainiqolo *et al*. 2016). Four experimental studies examining the effect of pharmacological doses of kavalactones (≤300 mg/d) using computer-based driving simulation have shown slowed reaction time, and the visuo-motor performance on driving simulation was significantly impaired when kava was consumed with alcohol (Wainiqolo *et al*. 2015).

If higher doses of kava are used when driving and operating heavy machinery, caution is advised, as visual attention may be possibly impaired under cognitive demand. In addition, caution is also advised when ingesting kava with alcohol or other substances, as deficits in attention, accuracy and concentration may occur (Foo and Lemon, 1997).

In Utah, a 44 yr old was convicted of 'driving under the influence' after ingesting 16 cups of kava beverage as his driving was impaired and was stopped for swerving in and out of traffic lanes (Deseret news, Aug.5, 1996). Similarly, in California, there were two cases of drivers arrested for 'driving under the influence' after ingesting kava tea. Neither of them was prosecuted.

Cardiovascular effect

A cross-sectional study in the Arnhem Land Aboriginal community revealed that kava's health effects include seizures and extreme weight loss in heavy users (up to 20% of body mass), Raised total and low-density lipoprotein (LDL) cholesterol levels may be a risk factor for cardiovascular disease and sudden cardiac deaths. Potential immunosuppressive effects are suggested by relative lymphocytopenia in heavy kava users. It has been associated with increased red blood cell volume, reduced platelet volume, and reduced serum albumin (Clough et al. 2003). In heavy kava users, tachycardia, electrocardiogram abnormalities (tall P waves-sign of right atrial enlargement) and shortness of breath have been reported (Mathews et al. 1988). P wave abnormalities reflect pulmonary hypertension.

Systemic effects associated with excessive kava use are hepatotoxicity, malnutrition, weight loss, renal dysfunction, and depression of plasma proteins, platelet and lymphocyte levels.

Neurological

Intoxicated kava drinkers (who consumed 205g of kava powder (approximately 150-times clinical doses) showed ataxia, tremors, sedation, blepharospasm and elevated liver enzymes (GGT, and alkaline phosphatase), together with saccadic dysmetria, saccadic slowing, and reduced accuracy performing a visual search task. Kava elicits a dose-dependent psychotropic effect. Kava intoxication is characterized by specific abnormalities of movement/motor coordination and visual attention but normal performance of complex cognitive functions. Saccade abnormalities suggest disruption of cerebellar and GABAergic functions (Cairney et al. 2003a).

A double-blind, randomized, placebo-controlled study in participants with generalized anxiety disorder (GAD) (n = 75) treated with either an aqueous extract of kava (120/240 mg kavalactones), for 6 weeks observed moderate effects on reducing anxiety in the kava group (Hamilton Anxiety Rating scale, HAMA) compared to placebo. However, more headaches were reported within the kava group, GABA transporter polymorphisms were associated with HAMA reduction. The authors conclude that standardized kava may be a moderately effective short-term treatment option for GAD (Sarris et al., 2013c).

Kava may also cause adverse neurological effects and cause excessive perioperative sedation. Such a reaction may be due to benzodiazepine and antidepressant activities on noradrenergic and/or serotoninergic pathways that may potentiate benzodiazepine and induction anesthetic potency (Raduege et al. 2004). A review implicates kava use to effect electroconvulsive therapy outcome in patients due to its neurological actions (Patra and Coffey, 2004). Several cases of central dopamine antagonism have been reported after short-term use (1 –4 days), including torticollis, oculogyric crisis and oral dyskinesias in young to middle-aged people, serious exacerbations of Parkinsonian symptoms (Schelosky et al. 1995; Meseguer et al. 2002)

Musculoskeletal effect

A case of rhabdomyolysis was reported in a 29-year old man after ingestion of an herbal product containing guarana (500 mg), ginkgo biloba (200 mg) and kava (100 mg) (Donadio et al. 2000). Another case of rhabdomyolysis associated with ingestion of large amounts of kava was reported where the 34-year old patient developed peak creatine phosphokinase levels in excess of 30,000 U/L but had no significant renal damage. The patient denied any other ingestions, medications, and excessive exertion (Bodkin et al. 2012).

VII. Drug, herb, and dietary supplement interactions

Kava displays a propensity for both pharmacokinetic and/or pharmacodynamic interactions with other drugs and herbs. This is of concern especially with drugs

that are metabolized by CYP1A2, CYP2C19, and CYP3A or those eliminated by P-glycoprotein, or that have sedative or hepatotoxic effects. Use of different kava cultivar varieties, plant parts other than the roots or contamination with mold hepatotoxins may increase toxicity. Co-administration of kava with acetaminophen (APAP) in mice indicated the possibility of kava potentiating APAP-induced hepatotoxicity. Further, the authors identified synergistic action of flavokavains A and B with APAP hepatotoxicity (Narayanapillai et al., 2014)

VIII. Overall Conclusion

After reviewing the available data and information, toxicology concludes that there is enough toxicological data that demonstrates that indiscriminate use of kava either as a "recreational" or "relaxation" beverage is not safe for human consumption. Moreover, there is no food additive regulation in effect that provides for the safe use of kava as an ingredient in conventional foods, and we are not aware of a basis for such use to be considered as generally recognized as safe (GRAS).

A safety determination for a substance that will be used as an ingredient in conventional food must be based on scientific studies appropriate to establish the safety of the substance under the conditions of its intended use. Further, the GRAS exemption requires not only the safety of the intended use of that substance but also that such safety is generally recognized by experts qualified by scientific training and experience to evaluate the safety of substances added to food. As discussed above in the overview of studies regarding the safe use of kava in foods, since the published literature and numerous case reports raise not only the known risk of hepatotoxicity but also several other adverse effects, we believe that the experts cannot come to a consensus regarding the safety of kava. There is sufficient evidence in rodents (NTP studies) for the carcinogenicity of kava extract. The relevance of such findings for humans cannot be ignored, especially when such neoplastic mechanisms were observed in the target organ, liver. The lack of adequate studies on kava preparations to assess any reproductive and developmental toxicities is also a concern. Additionally, kava has been shown to interact with a number of other drugs, herbs, and dietary supplements and co-administration of these substances with kava may lead to serious negative consequences.

In light of the safety concerns as discussed above, there is no basis to conclude that the use of kava as an ingredient in conventional foods is GRAS. Therefore, DFI/OFAS/FDA considers kava an unapproved food additive when used as an ingredient in conventional foods.

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U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Herbal Junction 3/11/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Seattle District
Pacific Region
22215 26th Avenue SE, Suite 210
Bothell, WA 98021

Telephone: 425-302-0340
FAX: 425-302-0402

March 11, 2016

VIA CERTIFIED MAIL
SIGNATURE REQUIRED

In reply refer to Warning Letter SEA 16-09

Jerry L. Smith, Owner
Herbal Junction
PO Box 50041
Eugene, Oregon 97405

WARNING LETTER

Dear Mr. Smith:

The United States Food and Drug Administration (FDA) inspected your processing facility, located at 50 East 25th Avenue, Eugene, Oregon, from May 26 - 29, 2015, and June 4, 2015. At this facility, you manufacture herbal enzyme elixirs that you market as dietary supplements. The liquid concentrates, coolers, herbal infusions, power tonics, tinctures and bars manufactured at this facility are marketed as conventional foods.

During the inspection, we evaluated your dietary supplement manufacturing, packaging, labeling and holding operations for compliance with Title 21, Code of Federal Regulations (21 CFR), Part 111. Your dietary supplement products comprise: Herbal Enzyme Elixir Cosmic Think Drink Herbal Supplement, Herbal Enzyme Elixir Exotic Dream Herbal Supplement, Herbal Enzyme Elixir Liver Tea and Justice Herbal Supplement, Herbal Enzyme Elixir Flower Power Herbal Supplement, Herbal Enzyme Elixir Ginger Alchemy Herbal Supplement, Herbal Enzyme Elixir Mate Way Herbal Supplement, Herbal Enzyme Elixir Love Potion #9 Herbal Supplement, Herbal Enzyme Elixir Amazon Nectar Herbal Supplement, Herbal Enzyme Elixir Around the World Herbal Supplement, Herbal Enzyme Elixir Scarlet Ambrosia Herbal Supplement, and Herbal Enzyme Elixir Velvet Vision Herbal Supplement. The inspection revealed significant violations of the dietary supplement Current Good Manufacturing Practice (CGMP) regulations (21 CFR Part 111). These violations cause your dietary supplement products to be adulterated within the meaning of section 402(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(g)(1)] in that they have been prepared, packed, or held under conditions that do not meet the CGMP regulations for dietary supplements.

During the inspection, we also collected a sample of your Sky High Chai Organic Liquid Concentrate product. Based on your firm's practice of shipping this hermetically-sealed product in unrefrigerated conditions, combined with FDA sample results indicating product pH above 4.6 and water activity above 0.85, your Sky High Chai Organic Liquid Concentrate is a low-acid food product, as defined by 21 CFR 113.3(n). The inspection revealed serious violations of the low-acid foods regulation (21 CFR Parts 108 and 113). These violations cause your low-acid food product to be adulterated within the meaning of section 402(a)(4) of the Act [21 U.S.C. § 342(a)(4)], in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

Additionally, based on our review of product labels collected during the inspection, several of your products are misbranded under section 403 of the Act [21 U.S.C. § 343], as explained further below.

We received two e-mails from you on June 18, 2015, and June 19, 2015, concerning the observations noted on the Form FDA 483, Inspectional Observations, which was issued to your firm. We requested you submit a written response, and we subsequently received your written response to the FDA 483 on July 7, 2015. We address your response received July 7, 2015, below, in relation to the adulterated dietary supplements and adulterated low-acid food violations.

Adulterated Dietary Supplements

Our inspection revealed the following violations of the dietary supplement CGMP requirements:

1. You failed to establish a specification for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of your dietary supplements and that your dietary supplements are packaged and labeled as specified in the master manufacturing record, as required by 21 CFR 111.70(a). Specifically, you stated during the inspection that you have not established component specifications [21 CFR 111.70(b)], in-process specifications [21 CFR 111.70(c)], finished product specifications [21 CFR 111.70(e)] or labeling and packaging specifications [21 CFR 111.70(d) and 111.70(g)] for any of your dietary supplement products. Once you have established the required specifications, you must verify that the specifications are met in accordance with 21 CFR 111.73 and 111.75, and you must make and keep records in accordance with 21 CFR 111.95(b).

Your response is inadequate as it does not address the violation of failing to establish specifications. Your response states suppliers test the herbs used as components of your dietary supplements; however, you have not identified the specifications used for such testing, nor does your response address how you intend to comply with the requirement to establish in-process specifications, finished product specifications, and labeling and packaging specifications. Your response states that you are claiming an exemption under 21 CFR 111.75(d) from finished product verification, which is the requirement to verify that finished dietary supplements meet the specifications established for them (21 CFR 111.75(c)). However, finished product verification and establishing finished product specifications are separate and different requirements. There is no exemption from the requirement to establish finished product specifications.

2. You failed to prepare and follow a written master manufacturing record (MMR) for each unique formulation of dietary supplement that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch, as required by 21 CFR 111.205(a). During the inspection, you stated that your firm had not prepared MMRs for your dietary supplement products.

We are unable to evaluate the adequacy of your proposed corrective actions because, although your response stated that you had prepared handwritten MMRs that would be typed and maintained digitally, you did not provide us with any of these MMRs for review, nor did you provide us with a timeline of when these MMRs will be implemented for each unique formulation and batch size of dietary supplements that you manufacture.

3. You failed to prepare a batch production record (BPR) for each batch of dietary supplements manufactured, as required by 21 CFR 111.255(a). BPRs must include complete information relating to the production and control of each batch, as required by 21 CFR 11.255(b), and all of the required elements of a batch production record as listed in 21 CFR 111.260. Our investigator found that you failed to prepare batch production records, with the exception of a log where **(b)(4)** temperatures are routinely recorded. The temperature log is inadequate in that it fails to include all elements in 21 CFR 111.260.

Your response included a copy of a spreadsheet that you indicated is being designed, which documents the batch number, date, temperature and pH. This batch record template is insufficient in that it does not include all the elements required for a BPR, as provided in 21 CFR 111.260.

4. You failed to establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing, as required by 21 CFR

111.103. Specifically, you stated during the inspection that you have not established any quality control procedures.

We are unable to evaluate the adequacy of the proposed corrective actions with regard to quality control that are described in your response because you did not provide us with a copy of any written procedures for quality control operations, nor did you provide us with a timeline of when written procedures will be implemented. Further, even if you instituted the corrective actions described in your response as written procedures for quality control operations and implemented them in your facility, they would not adequately address the requirements for quality control operations in 21 CFR 111.103. For example, your proposed corrective actions do not include any procedures for making a disposition decision or approving or rejecting any processing. In addition, establishing once **(b)(4)** reviews of all manufacturing processes for your products would not meet the requirement for ensuring that all manufacturing processes meet written procedures because you must ensure that manufacturing processes are being adhered to **before** the products are shipped to customers (see 21 CFR 111.113). Further, your response says that quality control personnel will review all representative lots to ensure final products meet component specifications, but you cannot ensure component specifications have been met by testing a final product.

Guidance for small entities on how to comply with the CGMP regulations for dietary supplements is available online at **www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm238182.htm (/web/20160326074440/http://www.fda.gov/Food/default.htm)**.

Misbranded Dietary Supplements

5. Your herbal dietary supplement products are misbranded within the meaning of section 403(y) of the Act [21 U.S.C. § 343(y)] in that the labels fail to bear a domestic street address or domestic phone number through which the responsible person (as described in section 761 of the Act [21 U.S.C. § 379aa-1]) may receive a report of a serious adverse event with such dietary supplement.

Adulterated Low-Acid Food

6. Your firm failed to register with the FDA as a commercial processor of LACF products. A commercial processor of low-acid foods in hermetically sealed containers is required, not later than 10 days after first engaging in the manufacture, processing, and packaging of thermally processed low-acid foods in any state, as defined in section 201(a)(1) of the Act, to register and file a Form FDA 2541 (Food Canning Establishment Registration) with the FDA, as required by 21 CFR 108.35(c)(1). However, our inspection indicates that your firm processes LACF products, including but not limited to, Sky High Chai Organic Liquid Concentrate, without an LACF registration with the FDA. Your response is inadequate **(b)(3)**. LACF processors must register as commercial processors of low-acid foods, **(b)(3)**. To date, your firm has not registered with FDA as an LACF processor.

7. As a commercial processor engaged in the processing of low-acid foods packaged in hermetically sealed containers, you must, not later than 60 days after registration and prior to the packing of a new product, provide the FDA information as to the scheduled processes. This information must include the processing method, type of retort or other thermal processing equipment employed, minimal internal temperatures, times and temperatures of processing, sterilization value, or other equivalent scientific evidence of process adequacy, critical control factors affecting heat penetration, and source and date of the establishment of the process for each low-acid food in each container size, to comply with 21 CFR 108.35(c)(2). Specifically, your

firm has failed to file a scheduled process with FDA for the Sky High Chai Organic Liquid Concentrate that your firm manufactures. Scheduled process information for LACF products must be submitted on Form FDA 2541a (Food Process Filing For All Methods Except Low-Acid Aseptic). Additional information on registration and filing can be found in the publication "Establishment Registration & Process Filing for Acidified and Low-Acid Canned Foods (LACF)," available at: **www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/default.htm (/web/20160326074440/http://www.fda.gov/Food/default.htm)**. Scheduled processes must be established by qualified persons having expert knowledge acquired through appropriate training and experience in the thermal processing of low-acid foods in hermetically sealed containers, as required by 21 CFR 113.83.

Your response is inadequate as it states finished product samples of Sky High Chai Organic Liquid Concentrate will be evaluated by a process authority; however, this evaluation must occur before an LACF product is processed and distributed.

Your firm is responsible for determining which regulations apply to the products that you manufacture, including whether any of these products, including liquid concentrates, are considered low-acid canned foods or acidified foods, as defined in 21 CFR 113.3(n) and 21 CFR 114.3(b), subject to the applicable provisions of 21 CFR Parts 108, 113 and 114. Accordingly, your firm should determine or have determined for you whether any additional products that you manufacture are low-acid canned foods or acidified foods, and comply with the applicable requirements of 21 CFR Parts 108, 113 and 114, including process filing, for those products that are determined to be low-acid canned foods and acidified foods.

Adulterated Conventional Foods - Unapproved Food Additives

Any substance added to a conventional food must be used in accordance with a food additive regulation, unless the substance is the subject of a prior sanction or is generally recognized as safe (GRAS) among qualified experts for its use in foods [21 CFR 170.30(g)].

Several of your liquid concentrates, coolers, herbal infusions, and bars contain substances that are food additives as defined in section 201(s) of the Act [21 U.S.C. 321(s)]. These substances include, but are not limited to, the following:

- Kava kava used in Cocoa Mystic Cacao Herbal Elixir Infusion Liquid Concentrate, Kava Chai Liquid Concentrate, Cooler Exotic Dream Herbal Enzyme Elixir, Cooler Around the World Herbal Enzyme Elixir, Euphoric Espress [sic] Herbal Infusion, Kava Chai Herbal Infusion, Mystic Wild Jun Bar, Kava Kava Pacific Herb of Peace and Spirit Up Natural Herbs of Spirit;
- Jatoba used in Mate Rainforest Chai Liquid Concentrate, Cooler Ginger Alchemy Herbal Enzyme Elixir, Cooler Cosmic Think Drink Herbal Enzyme Elixir, Blue Heaven Herbal Infusion, Epic Espress [sic] Herbal Infusion, Mate Rainforest Chai Herbal Infusion, Cup of Health Herbal Infusion, Rainforest Energy Jun Bar, Rainforest Energy Tonic Natural Herbs of Endurance, and Extreme Energy Natural Herbs of Wake-fullness;
- Pau d'arco used in Cocoa Mystic Cacao Herbal Elixir Infusion Liquid Concentrate, Mate Rainforest Chai Liquid Concentrate, Cooler Mate Way Herbal Enzyme Elixir, Cooler Exotic Dream Herbal Enzyme Elixir, Cooler Amazon Nectar Herbal Enzyme Elixir, Cooler Around the World Herbal Enzyme Elixir, Mate Rainforest Chai Herbal Infusion, Cup of Health Herbal Infusion, Sweet Vanilla Mate Herbal Infusion, Rainforest Energy Jun Bar, Immune Solution Jun Bar, Mystic Wild Jun Bar and Spirit Up Natural Herbs of Spirit; and

- Ginkgo used in Cooler Mate Way Herbal Enzyme Elixir and Cooler Cosmic Think Drink Herbal Enzyme Elixir.

There is no food additive regulation which authorizes the use of kava kava, jatoba, pau d'arco or ginkgo. We are not aware of any information to indicate these substances are the subject of a prior sanction [see 21 CFR 181]. As explained below, we are not aware of any basis to conclude that these substances are GRAS for use in conventional foods.

FDA's regulations in 21 CFR 170.30(a)-(c) describe criteria for eligibility for classification of a food ingredient as GRAS. General recognition of safety must be based only on the view of qualified experts. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. In addition, general recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.

- Under 21 CFR 170.3(h), "[s]cientific procedures include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance." Under 21 CFR 170.30(b), "[g]eneral recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient." Section 170.30(b) further states that general recognition of safety through scientific procedures is ordinarily based upon published studies, which may be corroborated by unpublished studies and other data and information.
- Under 21 CFR 170.3(f), "[c]ommon use in food means a substantial history of consumption of a substance for food use by a significant number of consumers." Under 21 CFR 170.30(c)(1), "[g]eneral recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information." Importantly, however, the fact that a substance was added to food before 1958 does not, in itself, demonstrate that such use is safe, unless the pre-1958 use is sufficient to demonstrate to qualified experts that the substance is safe when added to food [21 CFR 170.30(a)].
- Under 21 CFR 170.3(i), "[s]afe or safety means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." The regulation provides that, in determining safety, the following factors are to be considered: (1) The probable consumption of the substance and of any substance formed in or on food because of its use; (2) the cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet; and, (3) safety factors which, in the opinion of qualified experts, are generally recognized as appropriate. Such safety factors ordinarily are established through extensive testing in animals to determine whether consumption of the ingredient produces adverse effects when consumed chronically (i.e., on a daily basis over the course of a lifetime).

We know of no basis for general recognition of safety for kava kava, jatoba, pau d'arco and ginkgo based either on scientific procedures or common use in food prior to January 1, 1958. In assessing the GRAS status of these substances for use in conventional foods such as yours, we considered the criteria described above. FDA is not aware of data to establish the general recognition of safety of these substances for use as an ingredient in conventional foods. Therefore, the use of these substances in your liquid concentrate, coolers, herbal infusion and bar products does not satisfy the criteria for GRAS status under 21 CFR 170.30.

8. FDA is not aware of any other exemption from the food additive definition that would apply to kava kava, jatoba, pau d'arco and ginkgo for use as ingredients in a conventional food. Therefore, these substances added to a conventional food are food additives under section 201(s) of the Act [21 U.S.C. § 321(s)] and are subject to the provisions of section 409 of the Act. Under section 409, a food additive is deemed unsafe unless it is approved by FDA for its intended use prior to marketing. Kava kava, jatoba, pau d'arco and ginkgo are not approved for use in any conventional food. Therefore, your liquid concentrates, coolers, herbal infusions and bars which contain kava kava, jatoba, pau d'arco and ginkgo are adulterated within the meaning of section 402(a)(2)(C) of the Act. These adulterated liquid concentrate products include Cocoa Mystic Cacao, Mate Rainforest Chai and Kava Chai varieties; cooler products include Mate Way, Exotic Dream, Ginger Alchemy, Amazon Nectar, Around the World and Cosmic Think Drink varieties; herbal infusions include Euphoric Espress [sic], Kava Chai, Blue Heaven, Epic Espress [sic], Mate Rainforest Chai, Cup of Health and Sweet Vanilla Mate varieties; and bars include Rainforest Energy Jun, Immune Solution Jun and Mystic Wild Jun varieties.

Misbranded Conventional Foods

9. Your Ginseng Journey Espress [sic] herbal infusion, Immune Solution Jun bar and Spirit Up tincture products are misbranded within the meaning of section 403(u) of the Act [21 U.S.C. § 343(u)] in that they purport to contain ginseng, but the purported ginseng ingredient is not from a plant classified within the genus Panax. Section 403(u) of the Act, added by the Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171), provides that the term "ginseng" may only be considered to be a common or usual name (or part thereof) for any herb or herbal ingredient derived from a plant classified within the genus Panax. Your Ginseng Journey Espress [sic] herbal infusion, Immune Solution Jun bar and Spirit Up tincture products contain an ingredient identified as Siberian Ginseng (*Eleutherococcus senticosus*). That ingredient may not be declared under a name that includes the term "ginseng" because it is not from the genus Panax. Although we did not review every product label or attempt to identify every misbranding violation, we noted that a number of your other product labels refer to ingredients that do not appear to be from the Panax genus as "ginseng." You should review all of your product labels to ensure that the term "ginseng" is not used in a way that misbrands the product.

10. Your Immune Solution Jun Bar and Field Trip Herbal Infusion are misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)] in that these products are fabricated from two or more ingredients, but their labels fail to bear the common or usual name of each ingredient in the product as required by 21 CFR 101.4(a)(1). Specifically, the ingredient statement for the Immune Solution Jun Bar declares "Jun culture" and "sucanat," which are not common or usual names of ingredients. Your ingredient statement must declare these ingredients by common or usual names that accurately identify or describe their basic nature or characterizing properties or ingredients (21 CFR 102.5) (e.g., for a culture, "bacteria and yeast culture" or "bacteria and mold culture"). "Jun culture" does not meet this requirement because it provides no information about the nature, properties, or ingredients of the culture. Similarly, "Sucanat" is a trade name used for marketing purposes, not a common or usual name that identifies or describes the basic nature or properties of the ingredient.

11. Your Cosmic Think Drink Herbal Enzyme Elixir product is misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)] in that it is a food which purports to be a beverage containing fruit or vegetable juice but the label fails to bear a statement on the information panel of the total percentage of such fruit or vegetable juice contained in the food [21 CFR 101.30(a)].

12. Your Field Trip Herbal Infusion product is misbranded within the meaning of section 403(e)(1) of the Act [21 U.S.C. § 343(e)(1)] in that the place of business of the manufacturer, packer, or distributor is not declared in accordance with 21 CFR 101.5. Specifically, the street address, city, state and zip are omitted from the label.

13. Your Cosmic Think Drink and Immune Solution Jun Bars are misbranded within the meaning of section 403(q) of the Act [21 U.S.C. § 343(q)] in that the label does not include a Nutrition Facts panel as required by 21 CFR 101.9.

The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of labeling violations. Other labeling violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

(b)(3)

This letter may not list all the violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. You are also responsible for ensuring that your processing plant operates in compliance with the Act, the CGMP dietary supplement regulation (21 CFR Part 111), the low-acid foods regulation (21 CFR Parts 108 and 113) and the food labeling regulation (21 CFR Part 101), and any other regulations that apply.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product, enjoin your firm from operating, and/or issue an Order of Need to obtain and hold a Temporary Emergency Permit.

We have the following comments regarding the labeling of your conventional food products:

- For your Ginseng Journey Espress [sic] Herbal Infusion product, if “Prince Ginseng” is not from the genus Panax, it may not be declared under any name that includes “ginseng.”
- Your Cosmic Think Drink Herbal Enzyme Elixir, Ginseng Journey Espress [sic] Herbal Infusion, Immune Solution Jun Bar, and Spirit Up tincture products do not list the street address of your place of business. The statement of the place of business shall include the street address, city, state, and ZIP code; however, the street address may be omitted if it is shown in a current city directory or telephone directory [21 CFR 101.5(d)].
- The ingredient statement for your Immune Solution Jun Bar product is not in the correct format. Currently, the product label contains two lists of ingredients, one for the entire bar and the other for the “Immune Solution” component of the bar. Because “Immune Solution” does not have an established common or usual name, it should not be listed as an ingredient of the bar (see 21 CFR 101.4(b)(2)). Rather, there should be only one ingredient statement on the product label and it should list all ingredients in the bar, including those that are components of “Immune Solution,” by common or usual name in descending order of predominance by weight in the finished product (the bar) (see 21 CFR 101.4(a)).

- We note that your Immune Solution Jun Bar ingredient statement declares “lecithin” as an ingredient. If this ingredient is from egg or soy, the ingredient statement does not meet the requirements of section 403(w)(1) of the Act, which states that specified allergens must be declared in the ingredient statement or in a “Contains” statement that immediately follows the ingredient statement.

- Your Field Trip Herbal Fusion Infusion product declares “stevia” in its ingredient list, but it is not clear from the ingredient list whether you are using stevia leaves, a crude stevia extract, or a purified extract in this product. If you are using stevia leaves or crude extracts obtained from stevia leaves in Field Trip Herbal Fusion Infusion or other conventional foods you produce, be advised that FDA considers these substances to be unsafe food additives when used in conventional foods (see FDA Import Alert 45-06, “Detention without Physical Examination of Stevia Leaves, Crude Extracts of Stevia Leaves and Foods Containing Stevia Leaves and/or Stevia Extracts,” **www.accessdata.fda.gov/cms_ia/importalert_119.html (/web/20160326074440/http://www.fda.gov/default.htm)**). As explained in the “Adulterated Conventional Foods” section of this letter, the use of an unsafe food additive in a conventional food adulterates the food under section 402(a)(2)(C) of the Act [21 U.S.C. 342(a)(2)(C)].

  However, FDA has reviewed GRAS notifications for the use of certain highly purified steviol glycosides obtained from stevia leaves as sweeteners in conventional foods, and has not objected to that use of these ingredients (see FDA Import Alert 45-06 for details on the composition and specifications of the highly purified steviol glycosides for which FDA has reviewed GRAS notifications without objection). If you are using such highly purified steviol glycosides in your product, please note that “stevia” refers to the botanical and is not the common or usual name of these highly purified ingredients. Rather, the common or usual name for highly purified steviol glycosides depends on the ingredient composition. If the sweetener is purified to contain 95 percent or more of a single steviol glycoside, the specific name of that single steviol glycoside is the common or usual name. For example, the name “rebaudioside A” should be used for ingredients with 95% or more rebaudioside A; the name “stevioside” should be used for ingredients with 95% or more stevioside. If the sweetener is purified to contain 95 percent or more of a mixture of two or more steviol glycosides, the name “steviol glycosides” would be the common or usual name.

We have the following comment regarding the labeling of your dietary supplements:

- Your herbal enzyme elixir dietary supplement products, include both a Supplement Facts panel and a Nutrition Facts panel. Only a Supplement Facts panel may be shown on dietary supplement products, and therefore the Nutrition Facts panel should be removed. See 21 CFR 101.36.

Section 743 of the Act (21 U.S.C. § 379j-31) authorizes FDA to assess and collect fees to cover FDA’s costs for certain activities, including re-inspection-related costs. A re-inspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved. Reinspection-related costs means all expenses, including administrative expenses incurred in connection with FDA’s arranging, conducting, and evaluating the results of the re-inspection and assessing and collecting the re-inspection fees [21 U.S.C. § 379j-31(a)(2)(B)]. FDA will assess and collect fees for re-inspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified noncompliance materially related to a food safety requirement of the

Act. Accordingly, FDA may assess fees to cover any re-inspection-related costs.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

Your written response should be sent to the following address: U.S. Food and Drug Administration, 22215 26th Avenue SE, Suite 210, Bothell, Washington 98021, to the attention of Katherine L. Arnold, Compliance Officer. Should you have any questions concerning this letter, you can contact Ms. Arnold at 425-302-0437.

Sincerely,
/S/
Miriam R. Burbach
District Director

cc: Oregon Department of Agriculture
Food Safety Division
635 Capitol Street NE
Salem, Oregon 97301-0110

More in 2016 (/web/20160326074440/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/default.htm)

Attachment L

From: Neil Cavanagh
To: English, Amber E.
Cc: Devon Reese; Dixon, Erin P.; Dick, Kevin
Subject: RE: EHS Meeting
Date: Thursday, June 15, 2023 4:04:28 PM
Attachments: image003.png
image002.png
image001.png

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That works, thank you.

Neil and Dalice Cavanagh

Sent from Yahoo Mail on Android

On Thu, Jun 15, 2023 at 3:36 PM, English, Amber E. <AEEnglish@washoecounty.gov> wrote:

> Thanks for the quick response, Neil. We will start the scheduling process with the FSHAB and let you know the date, time and location.
>
> Please be advised that this Board does not have a regularly scheduled meeting and we haven't had an appeal hearing in about 3 years. Scheduling for the Board members may be challenging this time of year as several of them participate in the many special events in the region. We will need to give them plenty of notice so we can ensure availability and a quorum. We are hoping to get this meeting scheduled for mid to late July.
>
> Please let me know if you have any questions and will let you know as soon as we have more information on the hearing.
>
> Thanks,
>
> **Amber English, REHS**
>
> Environmental Health Specialist Supervisor| Environmental Health Services Division | Washoe County Health District
>
> aeenglish@washoecounty.gov | (775) 433-4015| 1001 E. Ninth St., Bldg. B, Reno, NV 89512

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From: neilcavanagh1@yahoo.com <neilcavanagh1@yahoo.com>
Sent: Thursday, June 15, 2023 9:29 AM
To: English, Amber E. <AEEnglish@washoecounty.gov>
Cc: Devon Reese <reesed@reno.gov>; Dixon, Erin P. <EDixon@washoecounty.gov>; Dick, Kevin <KDick@washoecounty.gov>
Subject: RE: EHS Meeting

[**NOTICE:** This message originated outside of Washoe County -- **DO NOT CLICK** on **links** or open **attachments** unless you are sure the content is safe.]

Good morning Amber, yes we would like to start the appeal process to serve Kava as a tea in it's traditional form. Thank you.

Neil and Dalice Cavanagh

Sent from Yahoo Mail on Android

On Thu, Jun 15, 2023 at 9:14 AM, English, Amber E.

<AEEnglish@washoecounty.gov> wrote:

> Good morning, Neil,
>
> The following section of the Regulations of the Washoe County District Board of Health Governing Food Establishments (food establishment regulations) outlines the appeal process. I've also attached a flowchart detailing the process.
>
> If you wish to move forward with an appeal, please respond to this email with your intent to do so and we will use your response as the written request for an appeal within

10 days of our meeting on Monday, June 12, 2023.

Once a written notice is received, we will begin scheduling the hearing with the Food Protection Hearing and Advisory Board.

Please let me know if you have any questions.

240.105 Hearings, appeals

A. An aggrieved person may bring an appeal before the Food Protection Hearing and Advisory Board when:

1. Any permit, as required by these regulations, has been issued, denied, renewed, suspended, or revoked, and said action has adversely affected said person in any manner.

2. The Health Authority has taken any action pursuant to the authority of these regulations, which has adversely affected said person in any manner.

B. All appeals to the Food Protection Hearing and Advisory Board shall be initiated by filing a petition or written notice of appeal to the office of the Health Authority within ten (10) business days after the person bringing the appeal has received any order, been subject to any action, or has had a permit, required by these regulations, issued, denied, renewed or suspended by the Health Authority.

C. For serious or repeated violations of any of the requirements of these regulations or for interference with the Health Authority in the performance of his duties, the permit may be permanently revoked after an opportunity for a hearing before the Food Protection Hearing and Advisory Board. Before taking such action, the Health Authority shall notify the permit holder in writing, stating the reasons for which the permit is subject to revocation and advising the permit holder of the requirements for filing a request for a hearing. A permit may be suspended for cause pending its revocation or a hearing relative thereto.

D. The Health Authority may permanently revoke a permit after 10 days following service of the notice unless a request for a hearing is filed with the Health Authority by the permit holder within 10 days.

E. The hearing provided for in this section must be conducted by the Food Protection Hearing and Advisory Board at a time and place designated by the Health Authority. Based upon the record of the hearing, the Food Protection Hearing and Advisory Board shall make a finding and make recommendation to the District Board of Health to sustain, modify or rescind an official notice or order considered in the hearing.

F. After completion of the hearing, the findings and recommendation(s) of the Food Protection Hearing and Advisory Board, along with transcripts and evidence from the hearing, shall be transmitted to the District Board of Health who will make the final decision. In making its decision, the District Board of Health may affirm, modify or reverse the decision of the Food Protection Hearing and Advisory Board or refer the appeal back to the Food Protection Hearing and Advisory Board for additional

consideration.

G. If the appeal is referred back to the Food Protection Hearing and Advisory Board, the Food Protection Hearing and Advisory Board shall, within 30 days, unless good cause exists, rehear the appeal. The District Board of Health may make no more than one (1) referral back to the Food Protection Hearing and Advisory Board.

H. A copy of the written findings and the final decision by the District Board of Health shall be sent by certified mail, return receipt requested, to the permit holder by the Health Authority.

Amber English, REHS

Environmental Health Specialist Supervisor| Environmental Health Services Division | Washoe County Health District

aeenglish@washoecounty.gov | (775) 433-4015| 1001 E. Ninth St., Bldg. B, Reno, NV 89512

[WashoeEats.com]WashoeEats.com

From: Neil Cavanagh <neilcavanagh1@yahoo.com>
Sent: Monday, June 12, 2023 1:58 PM
To: English, Amber E. <AEEnglish@washoecounty.gov>
Cc: Devon Reese <reesed@reno.gov>
Subject: EHS Meeting

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Amber thank you and Kevin Dick for your time today, what would be the next step to start the appeal process with FHSAB.

Neil and Dalice Cavanagh

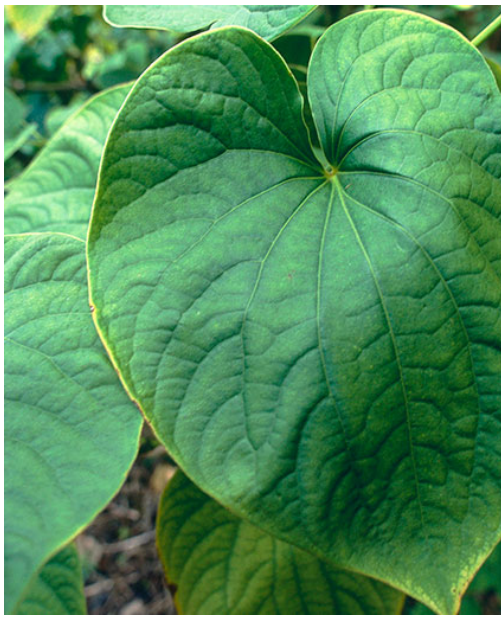
U.S. Department of Health and Human Services
National Institutes of Health

National Center for Complementary and Integrative Health

Kava

Common Names: kava, kava kava, ava pepper, ava root, kawa

Latin Names: *Piper methysticum*



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Background

- Kava is native to the islands of the western Pacific and is a member of the pepper family.
- Pacific islanders have used kava for thousands of years as a medicine and for ritual purposes.
- Today, kava is promoted as a dietary supplement for anxiety, insomnia, and other conditions.

How Much Do We Know?

- There has been a fair amount of research in people on the use of kava for anxiety, but few studies have been done on other conditions.

What Have We Learned?

- Kava supplements may have a small effect on reducing anxiety, but they have been linked to a risk of severe liver injury.
- There isn't enough evidence to show whether kava is helpful for any other conditions.

What Do We Know About Safety?

- The use of kava has been linked to liver injury that is sometimes serious or even fatal. The exact cause and frequency of the liver damage are unclear.

- Kava can cause digestive upset, headache, dizziness, and other side effects. The use of kava may affect the ability to drive or operate machinery. Long-term use of high doses of kava may cause kava dermopathy, a condition that involves dry, scaly, flaky skin with a yellow discoloration.
- Kava may have special risks if taken during pregnancy or while breastfeeding because of the presence of harmful pyrone constituents.

Keep in Mind

- Take charge of your health—talk with your health care providers about any complementary health approaches you use. Together, you can make shared, well-informed decisions.

For More Information

- Using Dietary Supplements Wisely
- Know the Science: How Medications and Supplements Can Interact
- Know the Science: How To Make Sense of a Scientific Journal Article

NCCIH Clearinghouse

The NCCIH Clearinghouse provides information on NCCIH and complementary and integrative health approaches, including publications and searches of Federal databases of scientific and medical literature. The Clearinghouse does not provide medical advice, treatment recommendations, or referrals to practitioners.
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Telecommunications relay service (TRS): 7-1-1
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Website: https://pubmed.ncbi.nlm.nih.gov/

Office of Dietary Supplements (ODS), National Institutes of Health (NIH)

ODS seeks to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, supporting research, sharing research results, and educating the public. Its resources include publications (such as *Dietary Supplements: What You Need To Know*) and fact sheets on a variety of specific supplement ingredients and products (such as vitamin D and multivitamin/mineral supplements).
Website: https://ods.od.nih.gov
Email: ods@nih.gov

Key References

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Last Updated: August 2020