RICHMOND CITY HEALTH DISTRICT | HENRICO COUNTY HEALTH DISTRICT

May 25, 2023

INFORMAL FACT-FINDING CONFERENCE REPORT
NOTICE OF VIOLATION AND OPERATION PERMIT DENIAL

Frederick Bryant Jr., President & CEO
Kava Club LLC
301 S 11th Street
Apt 2214
Richmond, VA 23219

Re: **DENIAL OF PERMIT AND FINDING OF VIOLATION** for KavaClub, 1529 W Main Street, Richmond, VA 23219

Date of Conference: April 13, 2023

Location: Henrico Health Department, 8600 Dixon Powers Drive, Henrico, VA 23228

Presiding Officer: Dr. Elaine Perry, MD, Health Director, Richmond and Henrico Health Districts

Participants: Fred Bryant, KavaClub Co-founder, President & CEO; DJ Lee, KavaClub Co-founder; Bram Crowe-Getty, KavaClub Product Manager; Justin Earley, KavaClub Lead Counsel; Chris Rohde, KavaClub counsel; Brad Copenhaver, Food Safety Consultant, Meadow View Strategies; Cindy McKelvy, Richmond and Henrico Health Districts (RHHD) Environmental Health Manager; Kirsten Dobson, Richmond City Health District(RCHD) Environmental Health Supervisor; Nancy Diersen, Office of Environmental Health Services State Food & Dairy Consultant; Joshua Laws, Senior Assistant Attorney General

INTRODUCTION

This Report provides a summary of the Informal Fact-finding Conference (IFFC) proceedings and my conclusions, which function as an agency case decision as defined in § 2.2-4001 of the *Code of Virginia*. The purpose of the IFFC was to allow you opportunity to provide additional information on KavaClub's permit application as specified in the recent Notice of Permit Application Denial dated March 28, 2023, and the Amended Notice of Permit

Application Denial dated April 4, 2023, to determine whether conditions at KavaClub violated the Board of Health's Virginia Department of Health Food Regulations (12VAC5-421 *et seq*.; Regulations).

The Board of Health is charged with the protection of the health and welfare of the citizens of the Commonwealth through the supervision of restaurant operation. (Va. Code § 35.1-1 *et seq*.). In accordance with *Code of Virginia* §§ 32.1-31 and 35.1-2, the State Health Commissioner delegated to me, the Health Director of Richmond and Henrico Health Districts, authority to enforce the Regulations within these Districts, including authority to conduct informal proceedings per *Code of Virginia* § 2.2-4019 and the Regulations at 12VAC5-421-3970 (Enforcement of Regulation).

BACKGROUND

Prior to the IFFC, I reviewed relevant agency documents (see attached correspondence) concerning KavaClub's intended operation and the observations and regulatory violations alleged by RHHD. Documents included the Notice of Permit Application Denial/Notice of Informal Fact-finding Conference dated March 23, 2023, and the Amended Notice of Permit Application Denial/Notice of Informal Fact-finding Conference dated April 4, 2023, related to these same agency observations, and recommendations for compliance.

Chronology:

1. On February 22, 2023, Environmental Health (EH) Supervisor, Kirsten Dobson became aware of a potential new facility named KavaClub to be located in the City of Richmond through a news article. Environmental Health Associate (EHA), Carley Schneider, contacted via email to the facility to inform them that RCHD had not yet received an application for permit or application for plan review.
2. On February 22, 2023, Carly Schneider, EHA received a phone message from Chris Rhode, a representative of KavaClub asking to speak about the application.
3. On February 23, 2023, Cindy McKelvy, EH Manager, spoke with Chris Rhode and explained that the facility would be regulated by the Virginia Department of Health and would need to submit an application and plan review in accordance with 12 VAC5-421-3660.
4. On February 27, 2023, RCHD received an application packet, including a plan review from KavaClub. The intended menu submitted with the KavaClub permit application lists beverages containing kava and kratom.

5. Kava and kratom are not Generally Recognized as Safe (GRAS)[1] nor approved food additives by the Food and Drug Administration (FDA). There are currently no FDA-approved uses for Kratom.[2]
6. On March 3, 2023, Cindy McKelvy, EH Manager, emailed the applicants and their representatives to inform them that kava and kratom are not currently GRAS or approved by the FDA as food additives. As such, RCHD could not approve menu items containing kava and kratom. Ms. McKelvy asked whether they wanted to amend their application to contain only the non-kava and kratom items or proceed as submitted.
7. On March 14, 2023, Brad Copenhaver, a representative of KavaClub requested a call with Olivia McCormick, Director, Division of Food and General Environmental Services to discuss the application. A meeting time was set (Microsoft Teams meeting) for March 15, 2023, at 2PM.
8. On March 15, 2023, a virtual meeting was held with Cindy McKelvy, Nancy Diersen, OEHS, State Food & Dairy Consultant, Karri Atwood, Director of Legal Services, Brad Copenhaver, and Justin Earley (counsel for KavaClub) in attendance. Kava Club representatives requested the meeting to discuss the application process.
9. On March 20, 2023, Cindy McKelvy received a letter in the form of a legal brief from Venable LLP and The Earley Legal Group as a supplement to the submitted KavaClub application.
10. On March 28, 2023, RCHD sent to KavaClub, LLC, a Notice of Permit Application Denial/Notice of Informal Fact-finding Conference via email and certified mail.
11. On March 30, 2023, Brad Copenhaver, KavaClub representative called Cindy McKelvy to request an earlier IFFC date. An earlier date of April 13th at 11AM at the Henrico Health Department was agreed upon by all parties.
12. On April 3, 2023, Richmond City Environmental Health staff observed KavaClub Instagram posts that appeared to indicate the facility may be operating without a valid health permit.
13. On April 4, 2023, RCHD sent to KavaClub LLC, an Amended Notice of Permit Application Denial/Notice of Informal Fact-finding Conference via email and certified mail.
14. April 13, 2023 —Presiding Officer Dr. Elaine Perry, District Health Director, conducted an IFFC at Henrico County Health Department, 8600 Dixon Powers Drive, Henrico, VA 23228.

APPLICABLE LAW (in part):

United States Food, Drug, and Cosmetic Act 21 U.S. § 321(s)

[1] "GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.
[2] See https://www.fda.gov/news-events/public-health-focus/fda-and-kratom.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include-**(1)** a pesticide chemical residue in or on a raw agricultural commodity or processed food; or**(2)** a pesticide chemical; or**(3)** a color additive; or**(4)** any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C. 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. 601 et seq.];**(5)** a new animal drug; or**(6)** an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

Virginia Code Sections

§ 35.1-2. Enforcement.
This title shall be enforced by the State Board of Health and the State Health Commissioner as executive officer of the Board, acting through duly designated officers.

§ 35.1-4. Applicability of Administrative Process Act.
The Administrative Process Act (§ 2.2-4000 *et seq*.) shall govern the procedures for rendering all case decisions, as defined in § 2.2-4001, and for issuing all orders and regulations promulgated pursuant to the authority of this title.

§ 35.1-7. Penalties, injunctions, civil penalties and charges for violations.
A. Any person willfully violating, or refusing, failing, or neglecting to comply with any regulation or order of the Board or Commissioner, or any provision of this title, shall be guilty of a Class 3 misdemeanor unless a different penalty is specified. Each day of violation shall constitute a separate offense.

§ 35.1-14. Regulations governing restaurants; advisory standards for exempt entities.
C. The Board may adopt any edition of the Food and Drug Administration's Food Code, or supplement thereto, or any portion thereof, as regulations, with any amendments as it deems appropriate. In addition, the Board may repeal or amend any regulation adopted pursuant to this subsection. No regulations adopted or amended by the Board pursuant to this subsection, however, shall establish requirements for any license, permit, or inspection unless such license, permit, or inspection is otherwise provided for in this title. The provisions of the Food and Drug Administration's Food Code shall not apply to farmers selling their own farm-produced products directly to consumers for their personal use, whether such sales occur on such farmer's farm or at

a farmers' market, unless such provisions are adopted in accordance with the Administrative Process Act (§ 2.2-4000 *et seq*.).

§ 35.1-18. License required; name in which issued; not assignable or transferable.
No person shall own, establish, conduct, maintain, manage, or operate any hotel, restaurant, summer camp, or campground in this Commonwealth unless the hotel, restaurant, summer camp, or campground is licensed as provided in this chapter. The license shall be in the name of the owner or lessee. No license issued hereunder shall be assignable or transferable.

Virginia Administrative Code Sections

12VAC5-421-10. Definitions.
"Additive" means either a (i) "food additive" having the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(s) and 21 CFR 170.3(e)(1) or (ii) "color additive" having the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR 70.3(f).

"Food" means (i) a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption or (ii) chewing gum.

12VAC5-421-350. Additives.
Food shall not contain unapproved food additives or additives that exceed amounts specified in 21 CFR Parts 170-180 relating to food additives; generally recognized as safe (GRAS) or prior sanctioned substances that exceed amounts allowed in 21 CFR Parts 181-186; substances that exceed amounts specified in 9 CFR 424.21(b), Subpart C; or pesticide residues that exceed provisions specified in 40 CFR Part 180 and exceptions.

12VAC5-421-500. Protection from unapproved additives.
A. Food, as specified in 12VAC5-421-350, shall be protected from contamination that may result from the addition of:
1. Unsafe or unapproved food or color additives; and
2. Unsafe or unapproved levels of approved food and color additives.

12VAC5-421-3660. Permits.
A. No person shall own, establish, conduct, maintain, manage, or operate any food establishment in this Commonwealth unless the food establishment is permitted as provided in this section. All permits shall be in the name of the owner or lessee. Permits shall not be issued to newly constructed or extensively remodeled food establishments until a certificate of occupancy has been issued by the Building Official. Only a person who complies with the requirements of this part shall be entitled to receive or retain such a permit.

IFFC PROCEEDINGS:

I began the IFFC by addressing the requirements governing the proceeding contained in Code of Virginia § 2.2-4019 (Informal fact finding proceedings). KavaClub representatives

acknowledged and confirmed they received adequate notice of the IFFC, had opportunity to review all documents relied upon by the agency to potentially reach an adverse case decision, and understood the proceeding was an opportunity to present any factual data, arguments, or proof associated with or relevant to the permit application. Procedural matters concluded with no party voicing an objection. I emphasized this was an informal proceeding with no cross-examination of those presenting evidence. The proceedings were recorded at the request of the named party with a court reporter contracted by the named party. All voiced an understanding and intent to comply with this request. The transcript of the proceedings was not provided to me or RCHD prior to this case decision.

KavaClub stated the following during the IFFC:

1. Mr. Bryant introduced the KavaClub representatives.
2. Mr. Earley presented a PowerPoint presentation highlighting the business plan of KavaClub, their operations, and their opinions as to why kava and kratom are safe foods not subject to FDA food additive regulation. Mr. Earley clarified that KavaClub would be serving an unprocessed, natural kava root tea brewed from the raw, dried and ground product.
3. Mr. Earley presented an estimated total damage incurred for the month of March to be $173, 951.55.
4. Mr. Bryant addressed the observation regarding the appearance of the facility operating through social media posts by stating that they do not have a point of sale and the posts were for promotional purposes only and that they have only served friends, family, and trained staff.

RCHD staff then discussed KavaClub's application history:

1. Ms. McKelvy reviewed the application timeline as stated above.
2. Ms. Diersen stated that VDH follows FDA guidance.
3. Mr. Laws asked the named party if they have anything demonstrating that FDA regards kava as a food. Mr. Early said that they have no written document stating so.
4. Ms. McKelvy clarified that serving to the public with or without monetary exchange still requires a health permit.
5. Ms. McKelvy inquired if KavaClub was trying to obtain GRAS notification for kava. Mr. Bryant and Mr. Early stated that they are not.
6. Ms. McKelvy stated that as it stands now, RCHD still understands kava and kratom to not be GRAS or approved food additives by the FDA.

Following presentation by both parties, I informed the IFFC attendants I would issue a case decision within 90 days regarding possible permit denial. After asking for any further comments or questions and hearing none, I adjourned the meeting at time 12:31PM on April 13, 2023.

FINDING:

1. **Kava and Kratom are unapproved food additives.**

During the IFFC, KavaClub presented evidence they intend to add ground kava and kratom root to water and serve to the public. Water is a food pursuant to § 12 VAC5-421-10 of the Regulations. The addition of kava and kratom to the food, affecting the characteristics of the food, water in this case, would make kava and kratom food additives pursuant to **§** 12 VAC5-421-10 and 21 U.S.C. **§** 321(s). As stated in the World Health Organization Report offered by KavaClub, "Kava beverage is said to have mild, pleasant psychoactive and intoxicating effects. ...Consumption of traditionally-prepared kava beverage is characterized by a state of mild intoxication, followed by muscle relaxation and eventual sleepiness."[3] Certainly, adding kava root to water would affect the characteristic of the water. Therefore, the only question is whether kava and kratom are GRAS. Kava Club stated that they did not seek GRAS certification from the FDA, instead stating that the use of kava and kratom have been widespread in the Pacific Islands for centuries. KavaClub did not provide peer- reviewed reports or evidence to prove these claims or to show that kava and kratom are safe for human consumption.

In its broadest sense, a food additive is any substance added to food. The United States Food, Drug and Cosmetic Act (the Act) refers to food additives as "any substance the intended use of which results or may reasonably be expected to result -- directly or indirectly -- in it's becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C. **§** 321(s). The Regulations cite to this definition in defining food additive in 12 VAC5-421-10. This definition includes any substance used in the production, processing, treatment, packaging, transportation or storage of food. As the FDA states on their website, the purpose of the legal definition, however, is to impose a premarket approval requirement[4]. Therefore, this definition excludes ingredients whose use is generally recognized as safe (where government approval is not needed), those ingredients approved for use by FDA or the U.S. Department of Agriculture (USDA) prior to the food additives provisions of law, and color additives and pesticides where other legal premarket approval requirements apply.[5]

FDA has the primary legal responsibility for determining the safe use of food additives.[6] To market a new food or color additive, a manufacturer or other sponsor must first petition FDA for its approval.[7] These petitions must provide evidence that the substance is safe for the ways in

[3]Kava: A review of the traditional and recreation consumption of the beverage. https://www.fao.org/3/i5770e/i5770e.pdf, section 1.3.

[4] FDA. (2010, April) *Overview of Food Ingredients, Additives& Colors.* **https://www.fda.gov/food/food-ingredients-packaging/overview-food-ingredients-additives-colors#foodadd**

[5] Id.

[6] FDA, Overview of Food Ingredients, Additives & Colors, https://www.fda.gov/food/food-ingredients-packaging/overview-food-ingredients-additives-colors

[7] FDA. n.d. *Food Additives & Petitions.* **https://www.fda.gov/food/food-ingredients-packaging/food-additives-petitions**

which it will be used[8]. Under the Food Additives Amendment, two groups of ingredients were exempted from the regulation process:

GROUP I - Prior-sanctioned substances - are substances that FDA or USDA had determined safe for use in food prior to the 1958 amendment. Examples are sodium nitrite and potassium nitrite used to preserve luncheon meats.
GROUP II - GRAS (generally recognized as safe) ingredients - are those that are generally recognized by experts as safe, based on their extensive history of use in food before 1958 or based on published scientific evidence. Among the several hundred GRAS substances are salt, sugar, spices, vitamins and monosodium glutamate (MSG).

When evaluating the safety of a substance and whether it should be approved, FDA considers: 1) the composition and properties of the substance, 2) the amount that would typically be consumed, 3) immediate and long-term health effects, and 4) various safety factors. The evaluation determines an appropriate level of use that includes a built-in safety margin - a factor that allows for uncertainty about the levels of consumption that are expected to be harmless. [9]

"GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the Act, any substance that is intentionally added to food is a food additive — and it is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive. Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food. Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive. General recognition of safety through scientific procedures is based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods. Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.[10]

According to Guidance published by the FDA[11], if a substance is not generally recognized as safe (GRAS) by qualified experts for its intended use in food and does not qualify

[8] Id.
[9] Id.

[10] See U.S. Food and Drug Administration, Generally Recognized As Safe (GRAS), https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras.
[11] See Guidance for Industry Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements, https://www.fda.gov/media/87680/download.

for any of the other exemptions from the food additive definition, it is a food additive. The guidance goes on to state:

Many substances intentionally added to beverages and other conventional foods are food additives. Food additives require premarket approval based on data demonstrating safety. Usually, these data are submitted to us in a food additive petition, although we may also approve a food additive on our own initiative without first receiving a petition. We issue food additive regulations specifying the conditions under which an additive has been demonstrated to be safe and, therefore, may be lawfully used. Any unapproved food additive used in a beverage or other conventional food causes the food to be adulterated under section 402(a)(2)(C) of the FD&C Act (21 U.S.C. 342(a)(2)(C)). Adulterated foods cannot be legally imported or marketed in the United States. If a substance is GRAS under the conditions of its intended use in food, it is exempt from the definition of a food additive, and thus, from pre-market approval. (See section 201(s) of the FD&C Act (21 U.S.C. § 321(s))). For a particular use of a substance to be GRAS, there must be both evidence of safety and a basis to conclude that this evidence is generally known and accepted by qualified experts. In other words, the GRAS standard first requires that the scientific evidence about the substance establish that the intended use of the substance is safe; i.e., that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use (21 CFR 170.3(i)). In addition, under the second part of the GRAS standard, the scientific evidence to establish the safety of the substance for its intended use must be generally available, and there must be a basis to conclude that consensus exists among qualified experts about the safety of the substance for its intended use (see 21 CFR 170.30(a)-(c)).[12]

The FDA is currently warning consumers not to use *Mitragyna speciosa*, commonly known as kratom, a plant which grows naturally in Thailand, Malaysia, Indonesia, and Papua New Guinea.[13] FDA is concerned that kratom, which affects the same opioid brain receptors as morphine, appears to have properties that expose users to the risks of addiction, abuse, and dependence.[14] According to the FDA website, there are no FDA-approved uses for kratom, and the agency has received concerning reports about the safety of kratom.[15] FDA is actively evaluating all available scientific information on this issue and continues to warn consumers not to use any products labeled as containing the botanical substance kratom or its psychoactive compounds, mitragynine and 7-hydroxymitragynine. FDA encourages more research to better understand kratom's safety profile, including the use of kratom combined with other drugs. Further, recognizing the potentially hazardous nature of kratom, the Virginia General Assembly passed Senate Bill 1108 in 2023, amending[16]the Virginia Consumer Protection Act by

[12] Id.
[13] https://www.fda.gov/news-events/public-health-focus/fda-and-kratom

[14] Id.

[15] Id.
[16] https://lis.virginia.gov/cgi-bin/legp604.exe?231+ful+CHAP0596

prohibiting the sale or offer for sale (i) any kratom product, defined in the bill, to a person younger than 21 years of age or (ii) any kratom product that does not provide a label listing all ingredients and with the following guidance: "This product may be harmful to your health, has not been evaluated by the FDA, and is not intended to diagnose, treat, cure, or prevent any disease." Until such time as the FDA finds kratom to be Generally Recognized as Safe, VDH cannot permit its use as a food additive.

KavaClub argues they are GRAS because of historic use in the Pacific Islands. This argument was not supported by scientific peer-reviewed reports or evidence to demonstrate extensive history of use in the United States before 1958 as provided in the Group II exemption to the FDA pre-market approval process noted above. Examples of additives FDA has listed as GRAS under this exemption are salt, sugar, spices, vitamins and monosodium glutamate (MSG).[17]

KavaClub alternatively argues kava and kratom are a dietary supplement, and therefore exempt from the definition of a food additive pursuant to 21 U.S. 321(s)(ff) and 12 VAC5-421-10. FDA regulates both finished dietary supplement products and dietary ingredients.[18]

In KavaClub's presentation during the IFFC and its application, they provided its plan to source the root of the kava plant (*piper methysticum*) from Fiji. KavaClub has given no indication that they intend to use a dietary supplement form of kava. Instead, they indicated they plan to process the ground root into water (a food) to brew a tea that will then be served to the public. Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994. A dietary supplement is a product intended for ingestion that, among other requirements, contains a "dietary ingredient" intended to supplement the diet. The term "dietary ingredient" includes vitamins and minerals; herbs and other botanicals; amino acids; "dietary substances" that are part of the food supply, such as enzymes and live microbials (commonly referred to as "probiotics"); and concentrates, metabolites, constituents, extracts, or combinations of any dietary ingredient from the preceding categories." To be a dietary supplement, a product must also be labeled as a dietary supplement; that is, the product label must include the term "dietary supplement" or equivalent.[19] KavaClub has not indicated any intention to use such commercially labeled product for sale to customers, instead choosing to add ground kava and kratom as unapproved food additives to water to brew a tea.

2. Operating without a permit.

On or about April 3, 2023, RHHD staff was made aware of several social media posts where it appeared Kava Club was operating as a restaurant without a permit. The social media post included a link, accessible to the public, to sign up for private tastings at KavaClub. Additional social media posts referenced a kava tasting that took place the previous day and a

[17] See *supra* FN3.
18Dietary Supplements, https://www.fda.gov/food/dietary-supplements

[19] FDA, Questions and Answers on Dietary Supplements, https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements

picture of two individuals holding beverages seated on couches within Kava Club. During the IFFC, KavaClub stated the social media posts entered into the record were of private events held with a small group of family, friends and staff, and were not open to the public.

A restaurant under 35.1-1 of the *Code of Virginia* is defined, in part, as "Any place where food is prepared for service to the public on or off the premises, or *any place where food is served, including lunchrooms, short order places, cafeterias, coffee shops, cafes, taverns, delicatessens, dining accommodations of public or private clubs."* (emphasis added). In addition, the Regulations further state in part, "No person shall own, establish, conduct, maintain, manage, or operate any food establishment in this Commonwealth unless the food establishment is permitted..." KavaClub did not deny serving food but only that it was not provided to the public for sale. Based on the testimony provided and the evidence in the record, it appears Kava Club operated as a restaurant without a permit.

CASE DECISION

Based on the above, and testimony provided at the IFFC, and documents in the case record, I determined sufficient evidence exists to find KavaClub's proposed operation violates the Regulations. Further, as Health Director of the Richmond and Henrico Health Districts and a medical doctor, I am concerned about the safety of the products proposed to be sold to the public. Little to no scientific peer-reviewed evidence was submitted to support the safety of these items — coupled with warnings from the FDA and the lack of GRAS certification — is such that I find kava and kratom to be unapproved food additives in violation of 12 VAC5-421-350. Further, as stated above, I find the applicant operated a food establishment without obtaining a permit as required by 12 VAC5-421-3660. KavaClub, to be operated by KavaClub LLC located at the address referenced above, seeks to operate in **VIOLATION** of the Code of Virginia § 35.1 *et seq*. (Hotels, Restaurants, Summer Camps, and Campgrounds) and the Virginia Department of Health Food Regulations (12VAC5-421 *et seq*.). As a result, **I DENY** the operation permit for this facility. Absent a permit to operate, you may **NOT OPERATE** upon receipt of this agency case decision.

I remind you, should you submit a new operation permit application for KavaClub, you must demonstrate full compliance with all applicable laws and have an inspection to verify the facility and operation practices meet the Regulations.

REQUIREMENTS FOR REGULATORY COMPLIANCE

1. Submit an amended application wherein kava and kratom are removed from the menu.
2. Obtain a permit to operate prior to preparing food service to the public.

RIGHTS OF THE NAMED PARTY

You may appeal this decision if adverse to your interests. An aggrieved party may request an adjudicatory hearing pursuant to, and in conformance with, *Code of Virginia* § 2.2-4020 (Formal hearings; litigated issues). Any request for a hearing must be in writing and received in the Office of the Commissioner no later than 30 calendar days from receipt of this case decision. Please address any appeal request to Ms. Julie Henderson, Director, Office of Environmental Health Services, Virginia Department of Health, 109 Governor Street, Richmond, Virginia 23219, or at julie.henderson@vdh.virginia.gov. You may also appeal this decision directly to the jurisdictional Circuit Court in accordance with *Code of Virginia* § 2.2-4026 and Rule 2A:2 of the Rules of the Supreme Court of Virginia[20].

Sincerely,

Elaine Perry, MD
Health Director
Richmond and Henrico Health Districts
(804) 501-4656
Elaine.Perry@vdh.virginia.gov

Cc: Fred Bryant, KavaClub Co-founder, President & CEO; Justin Earley KavaClub Lead Counsel; Chris Rohde, KavaClub counsel; Brad Copenhaver, Food Safety Consultant, Meadow View Strategies; Cindy McKelvy, RHHD EH Manager; Kirsten Dobson, RCHD EH Supervisor; Nancy Diersen, OEHS State Food & Dairy Consultant; Joshua Laws, Senior Assistant Attorney General; Karri Atwood, Director of Legal Services (OEHS)

Enclosures: Notice of Permit Application Denial
Amended Notice of Permit Application Denial
PowerPoint Presentation presented by KavaClub LLC

[20] Any party appealing from a regulation or case decision shall file with the agency secretary, within 30 days after adoption of the regulation or after service of the final order in the case decision, a notice of appeal signed by the appealing party or that party's counsel. With respect to appeal from a regulation, the date of adoption or readoption shall be the date of publication in the Register of Regulations. In the event that a case decision is required by § 2.2-4023 or by any other provision of law to be served by mail upon a party, 3 days shall be added to the 30-day period for that party. Service under this Rule shall be sufficient if sent by registered or certified mail to the party's last address known to the agency.