

From: [Poitevien, Erika](#)
To: [Luna, Nick](#)
Cc: [Lockeed, Matthew](#)
Subject: FDA Follow up
Date: Friday, September 1, 2023 2:31:00 PM
Attachments: [image001.png](#)

Hi Nick,

I hope all is well. Matt and I work with FDA's Office of Legislation. We recently received your inquiry regarding Kava and the "FDA's categorization of Kava as a dietary supplement, with a request to have it re-categorized as generally safe for consumption like any other consumable liquid."

We assume that you may be referring to a 2002 FDA Consumer Advisory ([Consumer Advisory: Kava-Containing Dietary Supplements May be Associated With Severe Liver Injury \(archive.org\)](#)). This advisory is no longer available on FDA's current website and can only be accessed via internet archiving sites, as we have linked to.

Kava is not always regulated as a dietary supplement; FDA regulates products based on various factors, including how they are labeled and the intended use of the product. For example, when Kava is used as a dietary ingredient in a dietary supplement, the applicable dietary supplement requirements apply. But kava can also be used to brew tea, for example, as described in the recently adopted Codex Alimentarius Regional Standard for Kava Products for Use as a Beverage When Mixed with Water, in which case different food requirements would apply. We note that FDA regulates dietary supplements differently from conventional food, or ingredients added to conventional food.

However, when Kava is an ingredient added to conventional food, we continue to have safety concerns for consumption of kava as an ingredient added to conventional food (e.g., kava added to a chocolate bar). This recently posted memo ([Scientific Memorandum: Kava \(8/11/2020\)](#)) describes our safety concerns. Our memo documents FDA's determination that the use or intended use of Kava as an ingredient in conventional food does not meet the statutory criteria for a generally recognized as safe substance and that Kava is an unapproved food additive. This determination does not apply to kava steeped in water and consumed as food or kava as a dietary ingredient in dietary supplements.

Please let us know if we can further assist and help answer additional questions that you might have.

Sincerely,

Erika

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Erika Poitevien
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