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THE FOOD SAFETY LAW FIRM

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VIA ELECTRONIC MAIL

James "Jim" Jones
Deputy Commissioner for Human Foods
U.S. Food & Drug Administration
Jim.Jones@fda.hhs.gov

Re: Status of Tara Flour, a Novel Ingredient not Generally Recognized As Safe, in the United States

Dear Mr. Jones:

I write you on behalf of hundreds of Americans who were made sick by two nearly simultaneous food-borne illness outbreaks; the first is associated with Daily Harvest's French Lentil + Leek Crumbles, and the second is associated with Revive Superfoods' Mango & Pineapple Smoothies. Some of these victims are children. And still others are grappling with persistent on-going health issues.[1]

Both contaminated food products mentioned above contained tara flour—a novel ingredient from Peru that is not classified as Generally Recognized as Safe (GRAS) nor approved as a food additive in the United States. I write with the hope that you might prevent further harm caused by this ingredient.

Scientific studies published in peer-reviewed journals report that exposure to, and consumption of, tara flour has already caused bodily injury to hundreds of American and Canadian consumers. In response, the Canadian Food Inspection Agency (CFIA) issued a notice on September 28, 2023, advising businesses to cease the sale and procurement of tara flour or any products incorporating it, citing its classification as a "novel food" that "has not been assessed for

[1] Marler Clark represents 339 of the approximately 470 consumers sickened in the Daily Harvest Crumbles outbreak, and 33 individuals affected in the Revive Superfoods' Smoothie outbreak. Among these, nearly 40 individuals underwent gallbladder removal surgery (cholecystectomy) and hundreds were hospitalized due to illness.

safety by Health Canada."[2] I urge the Food & Drug Administration (FDA) to take similar action in response to these findings.

The evidence shows that the cause of the Daily Harvest outbreak was tara flour, an ingredient manufactured by Molinos Asociados in Peru. This tara flour was imported from Peru to the United States by Smirk's, a Colorado company, and then supplied to Stone Gate Foods, a Minnesota-based manufacturer. Stone Gate Foods used this tara flour in the production of the Daily Harvest French Lentil + Leek Crumbles implicated in the outbreak.

On June 23, 2022, Daily Harvest recalled 28,000 units of its French Lentil + Leek Crumbles product produced between April 28 and June 17, 2022.[3] The recall followed reports of approximately 470 consumers who experienced illness or adverse reactions after consuming Daily Harvest's tara-flour-containing French Lentil + Leek Crumbles. Many consumers experienced symptoms consistent with toxin poisoning, directly impacting the liver and gallbladder. These symptoms included elevated liver enzymes, jaundice and scleral icterus, dark urine, gastrointestinal pain, and fatigue. Over 40 people had their gallbladders removed (cholecystectomy), and many continue to suffer from an array of ill effects from having eaten the Crumbles. On July 19, 2022, Daily Harvest issued a communication to its customers, informing them that internal investigations pinpointed tara flour sourced by Smirk's from Molinos Asociados as the root cause of the illnesses associated with its Crumbles product.[4]

Around the same time as the Daily Harvest outbreak, another subscription-based food company named Revive Superfoods was involved in a separate foodborne illness outbreak involving tara flour. Over thirty-five individuals who consumed Revive Superfoods' Mango & Pineapple Smoothies developed symptoms identical to, or substantially like, those symptoms experienced by individuals sickened in the Daily Harvest outbreak. The only common ingredient between Daily Harvest's French Lentil + Leek Crumbles and Revive Superfoods' Mango & Pineapple Smoothie was tara flour, which was sourced in both situations from Molinos Asociados.

Tara flour is an ingredient made from the seeds of a legume grown in South America, which Daily Harvest used as a plant-based protein in its Lentil + Leek Crumbles. While tara *gum*, a different product made from the same plant, has been used as a thickener in foods like ice cream, tara *flour* has not been widely used in North America, Canada, or anywhere else, and it is not "Generally Recognized As Safe" ("GRAS") nor approved as a food additive by the FDA. Nonetheless, tara was incorporated into two widely dispersed food products, and not one entity in either's chain of production has done anything to ensure the safety of this ingredient.

Congress created the GRAS designation in 1958 for those food additives with a long history of safe use in food. GRAS designation allows food companies to bypass the traditional premarket approval process for ingredients by showing that there is a consensus among scientific

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[2] Canada Food Inspection Agency. "Notice to industry: Tara protein powder (tara flour) not assessed for safety by Health Canada." Sept. 28, 2023. *See* Attachment No. 1.

[3] U.S. Food & Drug Administration. "Daily Harvest Issues Voluntary Recall of French Lentil + Leek Crumbles Due to Potential Health Risk." June 23, 2022. *See* Attachment No. 2.

[4] https://www.daily-harvest.com/content/french-lentil-leek-crumbles-advisory#

experts that a substance is safe for its intended use. Tara *flour* milled from the germ of tara seeds, however, is not GRAS. There is no evidence that the FDA received GRAS documentation for tara *flour* before Daily Harvest's Lentil + Leek Crumbles were designed, manufactured, promoted, and sold to the public.[5] To the contrary, based on all our extensive discovery and investigation to date, including a thorough search of FDA records, it is our understanding that Molinos never even attempted to seek GRAS status (or food additive approval) from the FDA for its tara flour. Furthermore, FDA's CORE Report states that, "while [Smirk's] did have an FSVP plan in place for tara protein flour, more information was needed for the investigation."[6] As you are undoubtedly aware, the FDA's Foreign Supplier Verification Programs (FSVP) mandate that U.S. importers, like Smirk's, oversee their foreign suppliers' adherence to FDA regulations. This is supposed to ensure that an approved importer in the United States will assume responsibility for ensuring that the products align with the FDA's FSVP requirements.

It has come to our attention that Molinos conducted its sole study on tara flour's potential for toxicity in January 2021 at the Universidad Peruana Cayetano Heredia. The study involved feeding tara to rats over a span of six weeks. It encompassed an evaluation of the rats' liver function through liver profile testing and an examination of the histology of their liver and kidney tissues. The study begs the question as to how Molinos knew to specifically test for liver function and whether there were prior indications or concerns about the potential for tara to cause liver injury. It also raises questions as to why Smirk's proceeded with the import and distribution of tara flour, especially given the absence of GRAS status for tara flour, the restricted scope of Molinos' study, and the paucity of other studies at the time.

On May 31, 2023, a scientific publication titled "Is Baikiain in Tara Flour a Causative Agent for the Adverse Events Associated with the Recalled Frozen French Lentil & Leek Crumbles Food Product? – A Working Hypothesis" appeared in the peer-reviewed scientific journal *Chemical Research in Toxicology*. The results of this study support a working hypothesis that the adverse events reported by individuals that consumed the Daily Harvest and Revive products were caused by the tara flour ingredient and were due, at least in part, to high levels of nonprotein amino acids (baikiain) in the tara flour. The study further hypothesized that in vivo metabolism of metabolically unstable baikiain results in a toxic metabolite that depletes glutathione and/or is an irreversible enzyme inhibitor (for L-pipecolate oxidase), resulting in adverse events which are dependent on the dose consumed and potentially exacerbated for individuals that have specific genetic predispositions.[7]

On September 14, 2023, another study titled "A food product as a potential serious cause of liver injury" was published in *Clinical Toxicology*. This research, conducted by the Department of Internal Medicine in Kingston, Canada, involved two patients who had consumed a "new

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[5] Neal D. Fortin. "The Legal Status of Tara in Food in the United States" *and* "A Discussion of Tara and GRAS Status," *Food Safety News*, Aug. 5, 2022. *See* Attachment No. 3.

[6] FDA Core Network. "Adverse Illness Event Series/Lentil and Leek Crumbles/Jun 2022 (CARA #1076) Incident Summary Report. Oct. 18, 2022. *See* Attachment No. 4.

[7] Chittiboyina, A.G., *et al*. 2023. Is Baikiain in Tara Flour a Causative Agent for the Adverse Events Associated with the Recalled Frozen French Lentil & Leek Crumbles Food Product? – A Working Hypothesis. 36(6):818-821. https://doi.org/10.1021/acs.chemrestox.3c00100. *See* Attachment No. 5.

smoothie product" containing tara flour in the same month. Both patients independently presented to the hospital with epigastric pain and acute liver injury, and they both experienced a recurrence of acute liver injury upon further consumption. While the study refrains from identifying the smoothie, it appears to be a thinly veiled reference to Revive's Mango & Pineapple smoothie. The authors of the study concluded that tara flour, a "natural ingredient" in the smoothie, was the cause of hepatotoxicity.[8]

Shortly after the publication of the second study, the Canadian Food Inspection Agency (CFIA) issued a notice to the industry, advising businesses to refrain from selling and purchasing tara flour or products containing tara flour due to its classification as a "novel food" that "has not been assessed for safety by Health Canada."[9]

At The Liver Meeting, held in Boston on November 10-14, 2023, a third study titled "Characterization of a Liver Injury Outbreak in 2022 After Ingestion of the Frozen French Lentil and Leek Crumble Food Product" was released.[10] The study aimed to delve deeper into the clinical aspects and underlying causes of the liver injury associated with the Crumbles. It specifically focused on 17 patients enrolled in the Drug Induced Liver Injury Network (DILIN), analyzing their clinical features, liver test abnormalities, liver histology, and conducting initial chemical analysis. The patients, with a mean age of 41 years, predominantly female (76%), and all Caucasian without pre-existing liver conditions, exhibited a median latency period of five days before symptom onset and an average of 18 days for symptoms to resolve. Symptomatically, the patients displayed a spectrum of manifestations including jaundice, nausea, fever, abdominal pain, and itching. Laboratory findings revealed elevated levels of liver enzymes, with median initial serum ALT at 369 U/L, AST at 117 U/L, alkaline phosphatase at 176 U/L, and total bilirubin at 2.7 mg/dL. The majority (53%) showcased a hepatocellular pattern of liver injury upon presentation, while the remaining cases exhibited mixed or cholestatic patterns. Further investigations, including a liver biopsy of one subject, displayed mild liver inflammation and necroinflammation indicative of acute hepatitis with an unknown etiology. Chemical analysis of four Crumbles samples revealed no presence of amatoxins, phallotoxins, aflatoxins, microcystins, pyrrolizidine alkaloids, or heavy metals within detectable limits, and phylogenetic analysis confirmed the inclusion of *Tara spinosa*, the source of tara flour, within the product. Since the removal of Crumbles from the market, no additional cases have been reported within the DILIN study. However, ongoing research endeavors aim to pinpoint the presumed hepatotoxin responsible for the liver injury and explore potential host factors, including genetic variants, that might predispose individuals to such adverse reactions.

We request that the FDA take actions like those initiated by the CFIA. Specifically, we request that the FDA issue a notice instructing businesses in the United States to cease the sale and acquisition of tara flour or any products containing it. It is alarming that, to date, tara flour can still be imported and sold as a food product in the United States without consequence. Additionally,

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[8] Chan, S. E., Smith, C.A. 2023. A food product as a potential serious cause of liver injury. https://doi.org/10.1080/15563650.2023.2256469. *See* Attachment No. 6.

[9] *See* Attachment No. 1.

[10] *See* Attachment No. 7. Available at: https://journals.lww.com/hep/fulltext/2023/10001/the_liver_meeting__boston,_massachusetts_nov.1.aspx

we call upon the FDA to conduct a thorough investigation in search of any efforts by anyone to obtain GRAS status for tara flour (we believe there were none), as well as Smirk's apparent failure to ensure that it and others acted in compliance with the FDA's Foreign Supplier Verification Programs regarding the importation of tara flour.

Very truly yours,

William D. Marler

WDM/km