

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

KATHLEEN MOLLER	*	CIVIL ACTION NO. 24-0228-WBV-DPC
	*	ALL CASES
	*	
VERSUS	*	JUDGE WENDY B. VITTER
	*	
MARTIAN SALES, INC; JOPEN, LLC,	*	MAGISTRATE DONNA PHILLIPS
a Texas limited liability company;	*	CURRAULT
JOHNSON FOODS, LLC, a Wyoming	*	
limited liability company; NUZA, LLC, a	*	
Wyoming limited liability company;	*	
CALIBRE MANUFACTURING, LLC, a	*	
Wyoming limited liability company; LP	*	
IND., LLC, a Wyoming limited liability	*	
company; CAG HOLDINGS, LLC, a	*	
Wyoming limited liability company;	*	
RMH HOLDINGS, INC., a Wyoming	*	
corporation; FMK GROUP, INC., a	*	
Wyoming corporation; PNW	*	
HOLDINGS, LLC, a Wyoming limited	*	
liability company; CC US HOLDINGS,	*	
LLC, a Wyoming limited liability	*	
company; PEYTON SHEA PALAIO;	*	
MARK JENNINGS; EYAL DAVID	*	
GABBAY; and MARK REILLY.	*	
*****	*	

**PLAINTIFF’S MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL
SUMMARY JUDGMENT THAT OPMS SILVER KRATOM IS UNREASONABLY
DANGEROUS**

MAY IT PLEASE THE COURT:

Plaintiff respectfully submits this memorandum of law in support of its motion for partial summary judgment as to unreasonable dangerousness, pursuant to Federal Rule of Civil Procedure 56. Plaintiff seeks summary judgment that the OPMS kratom products are unreasonably dangerous as a matter of law, for their failure to provide adequate warning or instruction regarding known risks, and for an unreasonably dangerous design. In the alternative, Plaintiff seeks a declaration that OPMS kratom products are “adulterated” and “misbranded” under the Food, Drug and

Cosmetic Act (FDCA) (21 USC §§ 343, 350(b) & 352), and an order pursuant to Rule 56(g) recognizing certain enumerated facts, such as the absence of warning as to a risk of a death and the existence of alternative designs, as established for purposes of this case.

I. INTRODUCTION

The facts of this case are unusual in the product liability context, in that the case concerns injuries from a product that it is not approved for human consumption because there is no reasonable basis for the safety of kratom, but kratom has no purpose other than human consumption, and which is nevertheless widely and openly promoted and sold. See Exhibits 1 & 2 (Packages of OPMS discovered at the scene of Harmony Moller's death); see also, Exhibits 19 & 20 (explaining kratom is not approved for human consumption). Consequently, there are several facts that the Defendants cannot genuinely dispute, as this memorandum will explain. Taken together, these facts yield the unavoidable conclusion that OPMS kratom products are adulterated and misbranded under federal law, have an unreasonably dangerous design and fail to adequately warn users, and specifically failed to adequately warn Harmony Moller. They are therefore unreasonably dangerous, an element of Plaintiff's claim under the Louisiana Product Liability Act, for which she requests partial summary judgment.

Adequacy of warning is a generally a question of fact, *Jack v. Alberto-Culver USA, Inc.*, 949 So. 2d 1256, 1259 (La. 2007); *Bloxom v. Bloxom*, 512 So. 2d 839, 844 (La. 1987), *see also Stapleton v. Kawasaki Heavy Industries, Ltd.*, 608 F.2d 571, 573 (5th Cir. 1979). However, when the warnings provided by the manufacturer are specific to the circumstances of a claim, the adequacy of the warning oftentimes does not present an issue of fact, and an award of summary judgment is appropriate. *Gonsoulin v. Beta USA, Inc.*, No. CV 24-1005, 2025 WL 2171050, at *11 (E.D. La. July 31, 2025) (citing *Broussard v. Procter & Gamble Co.*, 463 F. Supp. 2d 596, 608-10

(W.D. La. 2006), *aff'd*, 517 F.3d 767 (5th Cir. 2008)). An issue over whether a product design is unreasonably dangerous is similarly one of fact, typically requiring expert evidence to prove. *See Gonsoulin*, at *12 (citing *Broussard*, 463 F. Supp. 2d at 611, and *McCarthy v. Danek Med. Inc.*, 65 F. Supp. 2d 410, 412 (E.D. La. 1999)). As will be seen, the facts of this case do not admit dispute over the inadequate warning and design defects of the OPMS kratom products that killed Harmony Moller. They are unreasonably dangerous as a matter of law.

II. RECORD EVIDENCE IN SUPPORT / STATEMENT OF FACTS

Plaintiff has attached, or incorporates by reference, the following in support of this motion:

1. Plaintiff's Third Amended Complaint, Dkt. No. 100; and
2. Plaintiff's Statement of Material Facts and all Exhibits thereto.

III. PROCEDURAL HISTORY

Plaintiff filed an initial Complaint on January 24, 2024. Dkt. No. 1. A Second Amended Complaint was filed on February 6, 2024, to address deficiencies regarding Defendants' corporate citizenship noted by the Court. Dkt. No. 7. Almost all initially named Defendants moved to dismiss the Second Amended Complaint on May 9, 2024. Dkt. No. 31.¹ On July 16, 2024, this Court entered an order denying the motions to dismiss and ordered the parties to engage in jurisdictional discovery, in part to explore the single business enterprise and alter ego theories asserted in Plaintiff's Complaint. Dkt. No. 54.

The parties engaged in jurisdictional discovery, including the depositions of Martian Sales, LP, CAG, RMH, and Johnson Foods. Defendants also responded to written discovery.

¹ Johnson Foods, LLC filed a motion to dismiss on May 28, 2024. Dkt. No. 45.

Plaintiff filed a Third Amended Complaint on March 24, 2025, adding Nuza, Calibre, FMK, PNW, CC US, Palaio, Jennings, Gabbay, and Reilly as named parties. Dkt. No. 100. Defendants filed renewed motions to dismiss on May 23, 2025, arguing lack of personal jurisdiction and failure to state a claim. Dkt. No. 122. Plaintiff filed oppositions thereto on June 30, 2025. Dkt. No. 130. Plaintiff also filed a Motion for Partial Summary Judgment for a determination of veil piercing for jurisdictional purposes on June 30, 2025. Dkt. No. 132. Defendant's motions to dismiss and Plaintiff's Partial Motion for Summary Judgment remain pending. However, the parties are engaged in fact and expert discovery and now submit pre-trial motions.

IV. QUESTIONS PRESENTED

A. Have the Defendants failed to raise a genuine issue of material fact concerning whether OPMS kratom products, and specifically Green Vein Maeng Da kratom, are unreasonably dangerous products because an adequate warning has not been provided under La. R.S. §§ 9:2800.53 and 9:2800.57?

B. Have the Defendants failed to raise a genuine issue of material fact concerning whether OPMS kratom products, and specifically Green Vein Maeng Da kratom, are unreasonably dangerous products because their design is unreasonably dangerous according to La. R.S. § 9:2800.56?

C. In the alternative, have the Defendants failed to raise a genuine issue of material fact concerning the "adulterated" and "misbranded" status of OPMS kratom products under the FDCA?

D. Also in the alternative, have the Defendants failed to raise a genuine issue of material fact concerning the Plaintiff's proposed findings of fact?

V. LEGAL STANDARDS / STANDARDS OF REVIEW

A. **Motions for Partial Summary Judgment**

“The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56. Materiality is a matter of substantive law, and “[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). “A fact is considered material when its existence or nonexistence may be essential to plaintiff’s cause of action under the applicable theory of recovery.” *Smith v. Our Lady of the Lake Hospital, Inc.*, 639 So. 2d 730, 751 (La. 1994). “A genuine issue is one about which reasonable persons could disagree.” *Hines v. Garrett*, 876 So. 2d 764, 765 (La. 2004). In determining whether a genuine issue of material fact exists, the court must view all evidence in the light most favorable to the nonmoving party. *Scott v. Harris*, 550 U.S. 372, 380 (2007). The party asserting that a material fact “cannot be or is genuinely disputed” must support the assertion by either:

- (1) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials; or
- (2) showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.

Fed. R. Civ. P. 56(c)(1)(A)–(B).

If the moving party has carried its burden, the non-movant must “come forward with ‘specific facts showing that there is a genuine issue for trial.’” *Matsushita Elec. Indus.*

Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). The nonmoving party, however, cannot satisfy his summary judgment burden with conclusory allegations, unsubstantiated assertions, or only a scintilla of evidence. *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994) (en banc). “One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses[.]” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–24 (1986). If a party bears the burden of proof “to establish the existence of an element essential to that party’s case,” but fails to make a sufficient showing, “Rule 56(c) mandates the entry of summary judgment” against the party. *Id.* at 322.

B. Reasonably Anticipated Use

For all LPLA claims, a plaintiff must show that her damages relate to a reasonably anticipated use of the product. *Kampen v. American Isuzu Motors, Inc.*, 157 F.3d 306, 309 (5th Cir. 1998) (en banc); La. R.S. § 9:2800.54(A). The LPLA defines a reasonably anticipated use as “a use or handling of the product that the product's manufacturer should reasonably expect of an ordinary person in the same or similar circumstances.” La. R.S. § 9:2800.53(7). “Reasonably anticipated use” includes those user actions the manufacturer should have reasonably contemplated when designing the product and providing warnings. *See Kampen*, 157 F.3d at 311. Warning against a specific use does not necessarily relieve the defendant of its duty to design for and adequately warn against the associated risk. *Id.* at 314. A plaintiff may recover against a defendant who should have known its warning was being disregarded in a particular way. *Id.*, n.6 (citing RPlaintiffment, 3d of Torts, § 2 cmt. 1 (1998) (Warnings are not a substitute for safe design)). “A manufacturer must anticipate foreseeable misuse and also consider the particular hazard. When a product presents a serious risk of harm, the manufacturer must warn in a manner likely to catch the user's attention.” *Krummel v. Bombardier Corp.*, 206 F.3d 548, 551 (5th Cir. 2000) (citing

Delery v. Prudential Ins. Co. of Am., 643 So.2d 807, 813–814 (La. App. 4th Cir. 1994; quoting *Easton v. Chevron Industries, Inc.*, 602 So.2d 1032 (La. App. 4th Cir. 1992)).

C. Inadequate Warning

A product is unreasonably dangerous because an adequate warning about the product has not been provided if: (1) at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage; and (2) the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product. La. R.S. § 9:2800.57; *Gonsoulin v. Beta USA, Inc.*, 2025 WL 2171050, at *8 (E.D. La. July 31, 2025); *Couturier v. Bard Peripheral Vascular, Inc.*, 548 F. Supp. 3d 596, 609 (E.D. La. 2021). A plaintiff must demonstrate that the product has a potentially damage-causing characteristic and that the manufacturer failed to use reasonable care to provide an adequate warning about this characteristic. *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 264 (5th Cir. 2002). Before reaching the adequacy of the warning, however, a plaintiff must show that the injury arose from a ‘reasonably anticipated use’ of the product. *Gonsoulin*, 2025 WL 2171050, at *3 (quoting *Kelley v. Hanover Ins. Co.*, 722 So.2d 1133, 1136 (La App. 5th Cir. 1998)).

If the trier of fact then determines the inherent danger is not obvious, and the consumer is not aware of or trained to detect it, the adequacy of the warning must be scrutinized. *Warren v. Shelter Mutual Ins. Co.*, 233 So.3d 568, 574 (La. 2017) (quoting *Asbestos v. Bordelon, Inc.*, 726 So. 926, 955 (La. App. 4th Cir. 1998) and *Clark v. Jesuit High School of New Orleans*, 686 So. 2d 998 (La. App. 4th Cir. 1996)).² Regarding the adequacy of warnings, Louisiana’s pre-LPLA jurisprudence comports with the statute. *See Warren*, 233 So. 2d at 574.

² The text of *Asbestos* and other Louisiana decisions have mistakenly cited to an earlier decision on an unrelated issue in the *Clark* case, 572, So. 2d 830 (La. App. 4th Cir. 1990). The 1996 citation used in the body of this memorandum cites to the relevant failure to warn decision.

An “adequate warning” contains two components: “the warning must both lead the ordinary user or handler to contemplate the danger in using the product” and “to either use it safely or decline to use it.” *Stahl*, 283 F.3d 254 at 271 (quoting Thomas C. Galligan, Jr., *The Louisiana Products Liability Act: Making Sense of it All*, 49 LA. L. REV. 629, 677 (1989)); *Couturier* 548 F. Supp. 3d at 609 (E.D. La. 2021). An adequate warning “must be: (1) properly worded to signify the intensity of the inherent danger in the product; (2) properly placed on the product so that the consumer cannot avoid seeing it; and (3) it must convey to the consumer that injury or damage can result from a normal or intended use of the product. *Id.* To determine if a warning is adequate, Louisiana law considers the severity of the danger, the likelihood that the warning will catch the attention of those who may foreseeably encounter the risk, the intensity and form of the warning, and the cost of improving the strength or mode of the warning. *Gonsoulin*, 2025 WL 2171050 at *11 (citing *Bloxom v. Bloxom*, 512 So.2d 839, 844 (La. 1987); *Asbestos*, 726 So. 2d at 956 (citing *Clark* 686 So. 2d at 1002)).

D. Unreasonably Dangerous Design

Under the LPLA, a product's design is unreasonably dangerous if the plaintiff demonstrates that, at the time the product left the manufacturer's control, “[t]here existed an alternative design for the product that was capable of preventing the claimant's damage and that the danger of the damage outweighed the burden on the manufacturer of adopting the alternative design.” *Fuller v. Eisai Inc.*, 513 F. Supp.3d 710, 717-18 (E.D. La. 2021); *Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1198 (E.D. La. 2016); La. R.S. 9:2800.56. To determine whether an alternative design was capable of preventing the damage, Louisiana courts apply a cause-in-fact analysis that can use either or both “but for” and substantial factors tests. *Couturier*, 548 F. Supp. 3d at 608 (citing *Quick v. Murphy Oil Co.*, 643 So. 2d 1291, 1295 (La. Ct. App. 1994) and *Thomas v.*

Missouri Pacific R.R. Co., 466 So. 2d 1280, 1285 (La. 1985)). An alternative design need only reduce the likelihood or extent of damages, not completely prevent them. *Gonsoulin*, at *13; *see also Bernard*, 689 So. 2d at 560.

To conduct the risk-utility analysis, courts begin with determining what risk the product created, including the effect of a warning, if it was adequate. *Couturier*, 548 F. Supp. 3d at 608 (citing *Bernard v. Ferrellgas, Inc.*, 689 So. 2d 554, 560 (La. Ct. App. 1997)). They then ask if a reasonable person would conclude that the danger-in-fact, whether foreseeable or not, outweighs the utility of the product. *Couturier*, 548 F. Supp. 3d at 608; *Bernard*, 689 So. 2d at 561.

VI. ARGUMENT

A. **Because Human Consumption was a Reasonably Anticipated Use Regardless of Defendants' Disclaimers, the Defendants had a Duty to Design Against, and to Warn Harmony Moller of, the Risk of Death from Ingestion of OPMS Kratom.**

The Plaintiff has provided evidence demonstrating how kratom products, and their characteristic alkaloids including mitragynine, 7-Hydroxymitragynine (7-OH), and mitragynine pseudo indoxyl cause addiction, toxicity, and death in humans, *infra* at VI.B.1. In brief, kratom usage, especially when prolonged, can lead to addiction; to kratom toxicity, affecting multiple organs; and to cardiorespiratory arrest. See e.g. Exhibits 17, 18, 19, 20, 21, 29, 30, 38, 53, & 54.

The Plaintiff has also shown through competent evidence that OPMS kratom is knowingly sold with an expectation that buyers will ingest the product. It is not only foreseeable that users will ingest OPMS kratom, but the Defendants also expect the product to be used this way, and they market it for uses that require human consumption. See Exhibit 9 at 97:19-22; Exhibit 8 at 37:2-12; and Exhibit 32 (JOpen, LLC's Responses and Objections to Plaintiff's Requests for Admission at No. 9 ("Request For Admission No. 9: Admit that JOPEN Marketed and sold kratom products for human consumption. Response: Admit.")). In fact, Defendants intend for OPMS kratom to be

ingested for the unapproved medicinal purpose of assisting in the treatment of opiate use disorder. Exhibit 14 at 65:15-66:15; Exhibit 5 159:18-23 and pp.160:19-161:2; and Exhibit 4 at 206:23-207:10.

The self-serving disavowals on the Defendants' packaging, are not evidence of the contrary; rather, they illustrate the deceptive nature of the Defendants' business, conduct, and marketing practices. Exhibits 1 & 2 (Claiming OPMS Silver kratom is a "botanical specimen"). Defendants have offered no evidence that the purported benefits and purposes of OPMS kratom products could be achieved without human consumption.

The Defendants' description of OPMS kratom as a "botanical specimen" does not relieve them of their duties to safely design products, adequately warn against dangers and to avoid marketing adulterated and misbranded products. A "botanical specimen" intended for scientific, or research purposes would consist of a whole or partial sample of an actual plant, not a processed powder.³ Neither do scientists primarily obtain them in smoke shops, convenience stores, or health food stores. The noun "botanical," however, refers to "a drug made from part of a plant, as from roots, leaves, bark or berries." Collins English Dictionary, 2019. It is clear that Defendants are selling the latter "botanical specimen," and not the former.

For instance, Martian Sales agrees that a botanical specimen is "just a specimen of a botanical, like a piece of a leaf." Exhibit 9 (Excerpt of October 8, 2025, 30(b)(6) Deposition of Mark Reilly Corporate Representative of Martian Sales) at 97:1-4; see also, Exhibit 10 (Excerpt of October 9, 2025 30(b)(6) Deposition of Mark Jennings Corporate Representative of LP IND, LLC) at 35:17-21 (Stating "It's a plant or part of a plant."). Martian Sales also could not explain

³ See, e.g., "specimen," Collins English Dictionary, 2019: "A specimen is a single plant or animal which is an example of a particular species or type and is examined by scientists."

how a consumer would use OPMS kratom as a “botanical specimen.” Exhibit 9 at 97:7-17. OPMS Silver kratom labels also state that “*Mitragyna Speciosa* is an unapproved dietary ingredient.” Exhibits 1 & 2. Martian Sales confirms that is the case. Exhibit 9 at 98:3-7.

Further, the National Institute of Health (NIH) Office of Dietary Supplements, explains that a botanical is “a plant or plant part valued for its medicinal or therapeutic properties, flavor, and/or scent. Herbs are a subset of botanicals. Products made from botanicals that are used to maintain or improve health are sometimes called herbal products, botanical products, or phytomedicines.” Exhibit 56, <https://ods.od.nih.gov/factsheets/BotanicalBackground-Consumer/> (last accessed March 1, 2026). NIH explains that botanicals can be and regularly are regulated as dietary supplements, including when botanicals are used for human consumption and placed into mediums such as capsules for consumption. *Id.*

Human consumption of OPMS Silver kratom is the intended use. See, Exhibit 9 at 97:19-22; Exhibit 8 (October 8, 2025 Deposition of Mark Reilly in his Individual Capacity) at 37:2-12; and Exhibit 32 (JOpen, LLC’s Responses and Objections to Plaintiff’s Requests for Admission at No. 9 “Request For Admission No. 9: Admit that JOPEN Marketed and sold kratom products for human consumption. Response: Admit.”). “A warning against product *misuse* is relevant to assessing what uses of its product a manufacturer reasonably anticipates.” *Kampen*, 157 F.3d at 314.

The *en banc* U.S. Fifth Circuit discussed a hypothetical in *Kampen* that is on all fours with the case at bar:

Our holding will not...allow malevolent manufacturers to absolve themselves from liability for uses (or misuses) of their products which the evidence shows should have been reasonably anticipated despite a warning to the contrary.... It would be legally ineffective if, for example, Isuzu had warned against using its jack to change the tires on the Impulse, a user had nonetheless used the jack to change a tire and was injured in the process. In that case, a court should find that, despite the

warning, using a factory-supplied jack to change a tire (which is the very purpose for which the jack was supplied) is ...unquestionably a reasonably anticipated use.

Id., n.5. Defendants “warn” users that OPMS Silver is a “only for use as a botanical specimen,” and “cannot advise on its use” but intend that the product be ingested. Exhibits 1 & 2; see also, Exhibits 8, 9, and 32. This is exactly the same as a car manufacturer telling a purchaser not to use its jack to change a tire. As the Fifth Circuit instructs, this Court must find that ingestion is unquestionably a reasonably anticipated use of OPMS kratom products, and that Defendants’ “warning” is legally ineffective.

Because ingestion was a reasonably anticipated use of Defendants’ manufacture, distribution and sale of OPMS kratom products, and because ingestion may cause illness and death, the Court must analyze the Plaintiff’s failure to warn and design defects claims and evidence on their merits.

B. Defendants’ failure to adequately warn Harmony Moller and other kratom users of their risk of sudden death or instruct them on preventing it renders OPMS kratom products unreasonably dangerous under the LPLA.

1. OPMS kratom products contained the damaging and deadly ingredients mitragynine and 7-hydroxymitragynine upon leaving the Defendants’ control.

Defendants do not contest the presence of mitragynine and 7-OH in their product; on the rear of the package, in small print, they list the mass and content of percentage comprised of the deadly ingredients. Exhibits 1 & 2. Yet they fail to list the numerous other pharmacologically active alkaloids identified in product testing. See e.g., Exhibits 41-50 (product testing documents listing additional alkaloids present in the product at issue such as such as payantheine, speciogynine, speciociliatine, mitraphylline, and isoryhncophylline). The damaging characteristic of all identified and unidentified alkaloids was known to the manufacturer to be present, when the product left the manufacturers control.

While the Defendants may choose to maintain that the ingredients are not damaging or deadly, that position is false and known to them to be false. More importantly, they cannot marshal admissible evidence that raises a question of material fact concerning the dangers of kratom use, while the Plaintiff, Kathleen Moller, has presented overwhelming evidence of the dangers posed by these kratom alkaloids. Defendants rely on two extremely limited and narrow clinical studies, one profoundly biased as it is funded by Defendants themselves, for the proposition that kratom is safe. Yet their own experts acknowledge the studies are of insufficient power to render generalizable opinions to all kratom users and are not applicable to Harmony Moller specifically. See Exhibit 27 at 82:23-83:10 (Dr. Christopher McCurdy confirming that the Mitra-leaf study funded by Johnson Foods cannot be generalized to individuals with underlying cardiac conditions and polypharmacy); and 101:11-18 (Stating that none of the clinical studies relied on by Defendants are “of sufficient power to thoroughly characterize the safety profile of kratom...”); see also Exhibit 26 at 23:22-24 (Confirming Dr. Huestis’ clinical study of kratom was funded by [REDACTED]).

Indeed, the FDA has been reporting of dangers associated to Kratom since at least August 18, 2015, when it issued an import alert stating in part: “In fact, the scientific literature disclosed serious concerns regarding the toxicity of kratom in multiple organ systems. Consumption of kratom can lead to a number of health impacts, including respiratory depression, nervousness, agitation, aggression, sleeplessness, hallucinations, delusions, tremors, loss of libido, constipation, skin hyperpigmentation, nausea, vomiting, and severe withdrawal signs and symptoms.” Exhibit 18 (FDA Import alert listing for human and animal drugs, indicating Import Alter 54-15 was published on August 18, 2015, accessible at: https://www.accessdata.fda.gov/cms_ia/industry_66.html?utm_source%201/6, last accessed

February 26, 2026); Exhibit 19 (FDA Import Alert 54-15, accessible at: https://www.accessdata.fda.gov/cms_ia/importalert_1137.html, last accessed February 26, 2026); see also, Exhibit 21 (FDA and Kratom webpage warning of risks such a live toxicity, seizures, substance use disorder, and death, accessible at: <https://www.fda.gov/news-events/public-health-focus/fda-and-kratom>, last accessed February 26, 2026).

2. The dangers inherent in using OPMS kratom products are not obvious to its users.

OPMS kratom products appear to be a powder prepared for ingestion as a capsule or mixed in with a beverage. Exhibits 1 & 2. Because the sale of food, supplements, drugs and medicines is highly regulated, see FDCA, 21 U.S.C. § 301 *et seq.*, consumers encountering such products on the open market, in a store, do not have reason to consider them deadly. The dangerous kratom alkaloids, being an intrinsic, invisible component that is not detectable without chemical analysis, are inherently *not* obvious to a user. See Exhibits 41-50 (Product testing documents showing product contents and potency not listed on product labels (Exhibits 1 & 2)). Because OPMS kratom presents no obvious danger to a prospective consumer, the Defendants are required to provide an adequate warning of its dangerous content. *Warren*, 233 So.3d at 574; *Hooker v. Super Products Corp.*, 751 So.2d 889, 905 (La. App. 5th Cir. 1999); *Asbestos*, 726 So. at 955.

3. Defendants failed as a matter of law to use reasonable care to provide an adequate warning of the dangers of using OPMS kratom products, including the risk of death. or to instruct users how to avoid addiction, toxicity, or death when using the product.

a. Defendants’ warning was inadequate as to the risks of using their product.

The U.S. Fifth Circuit has noted that “a mere reference to an adverse effect is not necessarily an ‘adequate warning’ under the LPLA. The warning must contain language that is adequate to reasonably inform the recipient ... about the nature of the danger involved.” *Stahl*,

283 F.3d at 267. In the case at bar, the package warning does not even contain a single mention of the possibility of death, the ultimate “adverse effect.” See Exhibits 1 & 2. This alone is sufficient to render the Defendants’ warning inadequate to the risks run by their products’ users. Nor does it contain a mention of the possibility of addiction, let alone how addiction increases the chance of overdose and death. *Id.*, see also, Exhibits 17, 18, 19, 20, 21, 29, and 30.

The Plaintiff has proffered expert evidence as to the warning’s inadequacies. This evidence shows that the warning was insufficient under every factor Louisiana law considers. The record indicates the warning did not adequately present the severity of the danger. See generally, Exhibit 39 (Expert Report of Sarah Kowitt, Ph.D.). As already noted, the mention of death and addiction alone would not suffice to reasonably inform a prospective user of the danger. The warning requirement seeks to “lead the ordinary user or handler to *contemplate* the danger in using the product.” *Couturier*, 548 F. Supp. 3d at 609 (emphasis added).

In addition to the severity of the consequences, the placement, intensity and form of the warning provided are wholly inadequate to the risk of sudden death in the course of normal use. When a risk is deadly, the LPLA requires more than a laundry list of potential adverse effects in small print, which may not be read until after consuming the product. Rather, the size, location and prominence of the warning must be commensurate with the nature of the risk. Indeed, given Defendants easily changed labeling in the past, it should be easy to update the package warning label with changes such as clearly communicating the health risks associated to kratom (like cardiac adverse effects and risk of death), communicating how to minimize risks through clear guidance on dosage and timeframes for use, and by complying by warning best practices, such as use of clear familiar words, prominent placement of the warning, or use of icons or symbols to increase attention. See generally, Exhibit 39 (Expert Report of Sarah Kowitt, Ph.D.); see also,

Exhibit 5 at 67:1-17; 68:22-24 (discussing updating product labels to list the false distributor entity, Choice Organics).

“Numerous decisions confirm that the physical characteristics of the warning itself are pertinent to ... adequacy. The warning's conspicuousness, prominence, and size of print, in comparison to the print size employed for other parts of the manufacturer's message, must be adequate to alert the reasonably prudent person.” *Gonsoulin*, at 10 (quoting Madden, Owen & Davis, *Madden & Owen on Products Liability* § 9:10). In order for the warning or instruction to be adequate, it must also be expressed with an intensity proportionate to the danger inherent in the product. *Asbestos*, 726 So. 2d at 957 (citing *Ducote v. Liberty Mutual Insur. Co.*, 451 So.2d 1211 (La.App. 4 Cir.), *writ denied*, 457 So.2d 15 (La.1984)).

The Plaintiff's evidence shows that the warning was not adequately presented so as to lead an ordinary user to awareness, let alone to contemplation, of the risks of sudden death. See generally, Exhibit 39 (Expert Report of un rebutted warnings expert, Sarah Kowitt, Ph.D.).

Finally, the evidence shows that the costs of providing an adequate warning were miniscule and could never outweigh the lives a proper warning would save. For instance, when subject to a Utah enforcement action requiring listing a distributor on packaging, JOPEN responded by issuing stickers to update labels and then followed up with updated labels thereafter. Exhibit 5 at 67:1-17; 68:22-24.

The Plaintiff has filed evidence indicating what a sufficient warning would require. It shows that to draw users' attention and lead them to contemplation of the risk of death. Defendants, meanwhile, have not offered any admissible evidence that would establish a fact question as to the sufficiency of their warning.

b. OPMS kratom is “misbranded” under federal law, further demonstrating the Defendants’ failure to use reasonable care in labeling and warning users of its dangerous product.

OPMS kratom products do not comply with the laws and regulations on labeling dietary supplements and NDIs. See generally, Exhibit 31 (Expert Report of Evelyn Cadman). The Food, Drug & Cosmetic Act and the Dietary Supplement Health and Education Act impose specific labeling requirements for foods, drugs and new dietary ingredients. 21 U.S.C. §§ 343, 352; 21 C.F.R. § 101. Defendants have failed to abide by several provisions. *See, e.g.*, § 352(a),(f),(i), &(o); and § 343(e) & (y). Defendants testified to knowingly selling OPMS kratom products to people struggling with medical conditions, including opiate addiction, and testified to using kratom for this exact purpose as well. Exhibit 14 at 65:15-66:15; Exhibit 5 159:18-23 and pp.160:19-161:2; and Exhibit 4 at 206:23-207:10. When thus sold, it is recognized as a “new drug” under the FDCA. Exhibit 31 at p. 10; *see also* 21 U.S.C. § 321(p).

The FDCA prohibits the distribution and sale of “misbranded” food (including supplements and drugs) in interstate commerce. 21 U.S.C. § 331(a) and (b). A drug shall be deemed to be misbranded for any of the reasons specified under 21 U.S.C. § 352. OPMS kratom is “misbranded” for (1) lacking adequate directions for use; (2) not bearing adequate warnings against the dangers of normal use; (3) not bearing adequate warnings against unsafe dosage; and (4) false and misleading labeling.

A product sold as a drug (such as one aiming to treat pain) is misbranded when the labeling does not bear “adequate directions for use”. 21 U.S.C. § 352(f)(1). The directions must convey how a layperson can use the drug safely and for the purposes for which it is intended. 21 C.F.R. § 201.5. Here, Defendants instead disavow—on the product label—any ability to instruct on its

usage. Exhibits 1 & 2 (Stating in part “The manufacturers/re-seller of this product, therefore, cannot advise on its use.”) This is misbranding *per se*.

Drugs must also have “adequate warnings against use in those pathological conditions ... where its use may be dangerous....” 21 U.S.C. § 352(f)(2). There is no question that kratom is misbranded when there are no warnings of such dangers. *Id.* The only condition for which OPMS kratom warns against use is pregnancy. *Id.* There are many other conditions in which kratom consumption can be dangerous, respiratory depression, nervousness, agitation, aggression, sleeplessness, hallucinations, delusions, tremors, loss of libido, constipation, skin hyperpigmentation, nausea, vomiting, and severe withdrawal signs and symptoms. See Exhibit 19 (FDA Import Alert 54-15); see also, Exhibit 21 (FDA and Kratom webpage warning of risks such as a live toxicity, seizures, substance use disorder, and death).

OPMS kratom is also misbranded because its label does not bear “adequate warnings ... against unsafe dosage”. 21 U.S.C. § 352(f)(2). In fact, the “Directions” only state to “consult your healthcare professional to determine if this product is right for you...” Exhibits 1 & 2. However, Defendants’ medical experts admit they do not know what a safe or unsafe dose would be. See Exhibit 16 (Deposition of Dr. Boyer) at 82:8-11 (“Q: What is the maximum safe dose known for mitragynine? A: I don’t know that there are nay publications that define a maximum safe dose...”), 83:14-19 (“Q: Do you know the maximum safe dose for 7-hydroxymitragynine? ...A: I know that no maximum safe dose has been defined...); see also, Exhibit 26 (Deposition of Marilyn Huestis) at 125:1-22 and 312:20-313:1 (Q: How is someone supposed to know how much OPMS kratom to take?...The Witness: That I don’t know because it says talk to your physician about it.”). Users thus have no idea how much OPMS Silver kratom is safe to take, if any. There is no indication

that serious health effects and deaths have been linked to kratom usage, or other warnings against overdose.

A product sold as a drug is also deemed misbranded when “its labeling is false or misleading in any particular ...” 21 U.S.C. § 352(a)(1); see also 21 U.S.C. § 343(a)(1) (“false or misleading” standard for misbranded food); 21 CFR § 1.21 (label misleading if it omits facts material in light of other representations, or with respect to consequences that may result). OPMS kratom’s labeling is unquestionably misleading. Consumers will assume a product is safe based on the labeling. See e.g. Exhibit 56 (Describing how consumers assume natural botanical dietary supplements are safe). Here, the labeling’s only contraindication regards pregnancy, no maximum dosage is indicated and the only allusion to danger is confusing and vague. Exhibits 1 & 2, Exhibit 39. Moreover, kratom has known associations with addiction due to its impact on opioid receptors. See e.g., Exhibit 54 Stanciu, Corneliu N. et al., *What Is The Kratom Overdose Risk? A Systematic Literature Review*, Current Addiction Reports (2022) (Defense expert Christopher McCurdy listed as co-author and stating that “the currently available kratom products...greatly increase this [lethal toxicities] risk” as compared to traditional modes of consumption involving whole fresh kratom leaf); and Exhibit 29 (Dr. McCurdy indicating that kratom can be addictive).

Defendants’ labeling is also deceptive in that does not warn consumers that the FDA deems it adulterated. Exhibits 1 & 2. Defendants have been told directly by FDA that it is adulterated. See Exhibit 15 (Declaration of Evelyn Cadman) at Exhibit A-2 (FDA Inspection of JOpen, LLC stating in part “...a discussion was had regarding violative/adulterated products due to kratom. I explained to Mr. Gabbay that the FDA does not recognize kratom as an ingredient to be used in food items...”). OPMS packaging does not disclose that the reason kratom is “unapproved” is inadequate information to form an expectation that using it is reasonably safe. See e.g. Exhibit 19

(FDA Import Alert stating in part that given an absence of evidence establishing that kratom will reasonably be expected to be safe as a dietary ingredient, it is therefore adulterated.).

Finally, OPMS kratom does not comply with laws requiring the manufacturer, packer and distributor be accurately named, with contact information, on the label. 21 U.S.C. § 343(e). OPMS Silver kratom does not correctly identify the actual name and place of business for the entity responsible for the product. See Exhibits 1 & 2, identifying Choice Organics. The OPMS label identifies Choice Organics, and provides a phone number, address, and email. Exhibits 1 & 2. Choice Organics is an entity made up out of whole cloth in response to a Utah state enforcement action. Further, the address, phone number, and email have had periods in which they have not functioned. Exhibit 5 at 66:8-68:24, 79:19-81:3, 212:15-213:5, 219:17-220:4, & 239:24-240:20; see also, Dkt. No. 132-44 (Decl. of Leodler) at ¶ 22; see also, Exhibit 31 at pp. 14-16.

Defendants' noncompliance with federal labeling requirements renders its products misbranded as a matter of law. Marketing misbranded drugs and supplements is a violation of federal law and probative of Defendants' failure to use reasonable care when warning users of the dangers associated with OPMS kratom.

c. Defendants did not provide adequate instruction for users to safely consume their product.

Under the LPLA, even when a product is not defective, it can be unreasonably dangerous without adequate instructions from the manufacturer as to its safe use. *Krummel*, 206 F.3d at 551; *Summers v. FCA US LLC*, No. CV 23-1777, 2024 WL 3925169, at *9 (E.D. La. Aug. 23, 2024). The statute itself defines “adequate warning” as including “*instruction* that would lead an ordinary reasonable user...to contemplate the danger...and either to decline to use...or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made.” La.

R.S. § 9:2800.53(9) (emphasis added); *see also Tuminello v. ABC Insurance Co.*, 381 So.3d 320, 339 (La. App 3d Cir 2024), *writ denied*, 385 S.3d 702 (La. 2024).

The Plaintiff has also provided evidence as to instructions that any adequate warning must include such as clearly communicating the health risks associated to kratom (like cardiac adverse effects and risk of death), communicating how to minimize risks through clear guidance on dosage and timeframes for use, and by complying by warning best practices, such as use of clear familiar words, prominent placement of the warning, or use of icons or symbols to increase attention. See generally, Exhibit 39 (Expert Report of Sarah Kowitt, Ph.D.). Without these, users cannot know how to safely use OPMS kratom.

Defendants, however, provided Harmony Moller no information or instruction to take precautions to avoid or mitigate the possibility of death from of an unexpected reaction to their product or an inadvertent overdose. This is plainly visible on the product packaging. Exhibits 1 & 2. They have not introduced any evidence to raise a question of fact as to the absence of instructions concerning signs or symptoms that can signal severe injury or death. Nor have they provided evidence of instruction to the Plaintiff concerning emergency actions or precautions that could have mitigated the risk or prevented death. In the absence of any fact question concerning the adequacy of instructions for safe use of a deadly product, Plaintiff is entitled to summary judgment as to the unreasonable danger of OPMS kratom products.

C. Dangerous Design

1. A safer alternative design existed when the OPMS kratom left Defendants' control.

The Plaintiff has produced sufficient evidence to show that two alternative designs that would not have caused Harmony Moller to die existed at the time the OPMS kratom she used left Defendants' control. Alternative design 1 consists of the pure, fresh kratom leaf; to be consumed

in the manner it is in its native habitat. See Exhibit 40 (Dr. Christopher McCurdy discussing differences between kratom in U.S. versus Southeast Asia, where whole fresh leaf kratom is commonly used); Exhibit 54 (Stanciu, Corneliu N. et al., *What Is The Kratom Overdose Risk? A Systematic Literature Review*, Current Addiction Reports (2022), Christopher McCurdy is listed as a co-author and stating that “the currently available kratom products...greatly increase this [lethal toxicities] risk” as compared to traditional modes of consumption involving whole fresh kratom leaf); see also, Exhibit 27 at 154:21-156:5, 270:9-14, 276:5-24, 281:19-282:12 (Discussing oxidative processes that increase the presence of dangerous 7-hydroxymitragynine in kratom leaves after they are harvested, processed, and shipped). Fresh kratom leaf has existed since before *Mitragyna speciosa* was first scientifically documented in 1839.⁴ The Plaintiff’s evidence indicates that pure, fresh kratom leaf does not contain the dangerous characteristic 7-OH and thus presents a lower risk OPMS kratom. *Id.*; see also Chawarski, *Kratom consumed in Southeast Asia versus products consumed in the US*, National Inst. on Drug Abuse International Forum Research Abstract Database, <https://nida.nih.gov/international/abstracts/kratom-consumed-in-southeast-asia-versus-products-consumed-in-us>, (accessed Feb. 20, 2026). Serious adverse effects and fatalities are not associated with traditional use of fresh kratom leaf. Exhibit 54 (Stanciu, Corneliu N. et al., *What Is The Kratom Overdose Risk? A Systematic Literature Review*, Current Addiction Reports (2022), Christopher McCurdy listed a co-author and stating that “the currently available kratom products...greatly increase this [lethal toxicities] risk” as compared to traditional modes of consumption involving whole fresh kratom leaf); see also Chawarski. Pure, fresh kratom leaf product is therefore a safer alternative design, which existed when the OPMS product Harmony Moller used was purchased.

⁴ See *Mitragyna speciosa* Korth, <https://wfoplantlist.org/taxon/wfo-0000244943-2025-12> (World Flora Online).

Alternative design 2 is an unadulterated product that satisfies the requisite New Dietary Ingredient Notification standards. *See* Exhibit 31 at p7-8. While no unadulterated kratom product is yet on the market, a safer alternative design need not be in production at the time for purposes of the LPLA. To “exist” for purposes of § 9:2800.56, “does not mean that the alternative design must have been manufactured and in actual use when the manufacturer distributed his product. Nor does it mean that the alternative design must have been feasible, i.e., could have been employed even if was not, at that time.” Kennedy, *A Primer on the Louisiana Products Liability Act*, 49 La. L. Rev. 565, 596 (1989); *see also* *Hunt v. McNeil Consumer Healthcare*, 297 F.R.D. 268, 273 (E.D. La. 2014); *Wilson v. Hovart Corp.*, 1996 WL 117502, at *3 (E.D. La. Mar. 15, 1996). “‘Existed’ does mean that the alternative design must at least have been conceived at the time the product left its manufacturer’s control, because [a purpose] of the first element of section 2800.56 ... is to show that the manufacturer had a realistic choice as to design.” Kennedy, 49 La. L. Rev. at 596; *Hunt*, 297 F.R.D. at 273; *Wilson*, 1996 WL 117502, at *3.

Alternative design 2 did “exist” under Prof. Kennedy’s description when the OPMS kratom in this case was distributed. *See* Dkt. 100, Third Amended Complaint, at ¶ 40. Over a year before Harmony Moller’s death the FDA denied a *sixth* attempt for another kratom product to meet federal standards for use in a dietary supplement or as a dietary ingredient, which had been submitted August 30, 2021.⁵ Likewise, FDA denied Johnson Foods October 21, 2022 NDIN submission for a kratom product identified as NPI-001 (the basis of which is the Marilyn Huestis study defense experts rely on to support product safety). Dkt. 100 at ¶ 41-43. In fact, defense expert, Dr. Jack Henningfield, who has worked directly with Defendants regarding kratom, testified that it was in

⁵ <https://www.nutraingredients.com/Article/2022/02/02/Sixth-time-still-not-a-charm-FDA-again-rejects-NDIN-for-kratom/>; letter of November 5, 2021, FDA to redacted applicant, <https://www.regulations.gov/document/FDA-2021-S-0023-0081> (both accessed) Feb. 20, 2026.

the public interest for the OPMS product line to meet the safety standards required for an acceptable NDIN. See, Exhibit 31 at p. 8. Alternative design 2 has “existed” for purposes of the LPLA since at least the first such submission was made.

Moreover, alternative design 2 is “capable” of preventing that harm suffered by Ms. Moller. Capable means that the alternative design would have been significantly less likely than the chosen design to cause the damage for which the claimant has filed suit or that the alternative design would have significantly reduced such damage. See e.g., *Fuller v. Eisai Inc.*, 513 F. Supp.3d 710, 717-18 (E.D. La. 2021). The reasons FDA did not approve the Johnson Foods NDIN submission included that the “FDA was unable to establish the safety of your new dietary ingredient....FDA has concluded that prolonged daily consumption of kratom products containing mitragynine and its analogs can result in adverse effects such as tolerance and physical dependence, abuse, or additional potential, which may include...drug-drug interaction, and even death.” Exhibit 55 (January 24, 2023, FDA letter rejecting Johnson Foods’ NDIN submission for NPI-001). The alternative design, an acknowledged NDIN submission would at least satisfy the standard of “reasonably...expected to be safe,” by FDA. *Id.*

The FDA has explained to Johnson Foods and the kratom industry—that a product that fails to satisfy the requirements of alternative design 2 “may be adulterated...as a dietary supplement that contains a new dietary ingredient for which is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.” *Id.* at 3; see also, Exhibits 19-21. For purposes of this case, the letter indicates that the kratom industry, and Defendants specifically, are already aware of alternative design 2, and that marketing dangerous OPMS kratom instead was a choice Defendants made. There is no

genuine question that alternative design 2 is safer, or that it “existed” well before Harmony Moller obtained the OPMS kratom that killed her.

2. The danger OPMS products pose to kratom users outweighs the burden on Defendants of adopting either alternative design.

To establish liability, the Plaintiff must show that that the risk avoided (magnitude of damage discounted by the likelihood of its occurrence) by using one of the alternative designs would have exceeded the burden of switching to the alternative design (added costs and loss of product utility). *Thompson v. Nissan N. Am., Inc.*, 429 F. Supp. 2d 759, 776 (E.D. La. 2006), *aff’d*, 230 F. App’x 443 (5th Cir. 2007). The record shows that using alternative designs would unquestionably reduce significantly the magnitude and likelihood of damage, while the burden of switching is minimal since product utility would likely increase.

a. OPMS kratom poses a risk of grave harm, and the likelihood increases of injury increases with usage.

As the Plaintiff’s evidence makes plain, the harm OPMS kratom and similar products can cause is great. Users can die suddenly, with no knowledge that today’s kratom product has lethal amounts of dangerous characteristics. See generally Exhibits 19-21 (FDA warnings regarding kratom), Exhibits 22 & 23 (complaint reporting OPMS related deaths, predating the death in this matter), and Exhibit 55 (FDA rejection of Johnson Foods’ NDIN). Death, liver damage and other forms of organ poisoning are serious irreversible harms that pose great financial and emotional burdens on the victims and their families. See Exhibit 19 (FDA Import Alert 54-15). There is no known safe dose. See Exhibit 16 (Deposition of Dr. Boyer) at 82:8-11 (“Q: What is the maximum safe dose known for mitragynine? A: I don’t know that there are nay publications that define a maximum safe dose...”), 83:14-19 (“Q: Do you know the maximum safe dose for 7-hydroxymitragynine? ...A: I know that no maximum safe dose has been defined...); see also,

Exhibit 26 (Deposition of Marilyn Huestis) at 125:1-22 and 312:20-313:1 (Q: How is someone supposed to know how much OPMS kratom to take?...The Witness: That I don't know because it says talk to your physician about it."). There is no way for users to know how much of the active and/or dangerous ingredients they are consuming at a given time. Despite the quantification challenges, the Plaintiff has introduced the best scientific evidence available regarding the likelihood of harm.

Section 9:2800.56(2) requires consideration of the effect of an adequate warning on the risk to users. As explained in Part VI.A, *supra*, there is no adequate warning to take into effect in this case. To the extent the warning forms part of the risk-utility balancing test, the warning in this case actually increases the risk of harm, by falsely conveying the impression that a known safe dose exists and by omitting reference to the severity of potential injuries. See Exhibits 1 & 2, and Exhibit 39 (Expert Report of Sarah Kowitt). Because the harm OPMS kratom can cause includes severe injuries and death, and the likelihood of harm is not insignificant and grows with usage, the “risks” of OPMS kratom weigh heavily against any “utility” the product provides.

b. The utility of the existing design is not great but would increase through switching to the alternative designs.

Assessing utility requires consideration of the moral, social and economic utility of the product; both adverse and beneficial, of the alternative design on its utility; new or additional risks created by the alternative design; and the extent to which the alternative design would have prevented or eliminated the risk of the claimant's damage. Kennedy, 49 La. L. Rev. at 598-99. The Plaintiff's proof shows that the present utility of OPMS kratom is negligible. Its alleged principal use is treating opioid use disorder. Exhibit 14 at 65:15-66:15; Exhibit 5 159:18-23 and pp.160:19-161:2; and Exhibit 4 at 206:23-207:10. However, it may not be lawfully sold as a

treatment for these conditions, whether as a drug, as food, or as a dietary supplement. Exhibits 19 & 31; *see also*, 31 U.S.C. §§ 331, 342(f), 350b.

i. OPMS kratom is “adulterated” under federal law.

A “new dietary ingredient” (NDI) is defined as a dietary ingredient that was not marketed in the United States before October 15, 1992. 21 U.S.C. § 350b(d). The U.S. Food & Drug Administration (FDA) “considers kratom to be a new dietary ingredient under...” 21 U.S.C. § 350b(d). Exhibit 19 (FDA Import Alert 54-15). Before a, NDI can be legally sold for human consumption in the United States, a manufacturer must satisfy the FDA that it is “reasonably expected to be safe.” Exhibits 19 & 31, *see also*, 21 C.F.R. § 190.6. Federal law requires a manufacturer or distributor of a dietary supplement containing an NDI to submit a notification to the FDA at least 75 days before marketing for this purpose. Exhibits 31 & 55; *see also*, 21 U.S.C. § 350b(a)(2); 21 C.F.R. § 190.6. Without FDA’s determination that there exists adequate information that an NDI is reasonably expected to be safe, the NDI is deemed ‘adulterated’ under the law and may not be distributed or sold for human consumption. 21 U.S.C. § 342(f)(1)(B); Exhibits 31 & 55. FDA has repeatedly found that there is inadequate information to determine that kratom is reasonably expected to be safe. *Id.* For this reason, FDA has also banned the import of supplements “that are or contain *mitragyna speciosa* or kratom” since 2015 and renewed the ban February 21, 2025. Exhibit 19. Products containing kratom, such as OPMS kratom, are therefore “adulterated” as a matter of law and may not be sold for human consumption or the treatment of any disease. 21 U.S.C §§ 331, 342(f)(1)(B), 350b(a)(2); 21 C.F.R. § 190.6; *see also*, *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1080 (11th Cir. 2019) (“The sale of “adulterated” dietary supplements is expressly banned by the FDCA and the DSHEA. Further discussing the “presumption that a supplement containing a new dietary ingredient is unsafe....”

which may be overcome through a successful NDIN submission). As a product that cannot be lawfully sold for its principal use, the moral, social and economic utility of OPMS kratom is simply not discernable at law.

ii. The effects of the alternative designs would enhance product utility, while introducing limited, if any new risks.

The alternative designs would clearly decrease the likelihood of poisoning from that posed OPMS kratom. Fresh, pure kratom leaf, used traditionally does not contain the unnaturally elevated levels of mitragynine or 7-OH sometimes found in OPMS kratom. See Exhibit 40 (Dr. Christopher McCurdy discussing differences between kratom in U.S. versus Southeast Asia, where whole fresh leaf kratom is commonly used); Exhibit 54 (Stanciu, Corneliu N. et al., *What Is The Kratom Overdose Risk? A Systematic Literature Review*, Current Addiction Reports (2022), Christopher McCurdy listed a co-author and stating that “the currently available kratom products...greatly increase this [lethal toxicities] risk” as compared to traditional modes of consumption involving whole fresh kratom leaf); see also, Exhibit 27 at 154:21-156:5, 270:9-14, 276:5-24, 281:19-282:12 (Discussing oxidative processes that increase the presence of dangerous 7-hydroxymitragynine in kratom leaves after they are harvested, processed, and shipped). An “unadulterated” version of kratom would be “reasonably expected to be safe”. See e.g., Exhibit 31 and 55. At present, Defendants cannot even confirm which tests for potency relate to the products at issue, and cannot account for numerous alkaloids beyond mitragynine and 7-OH, which are both already demonstrably dangerous. Use of the alternative designs would have greatly reduced the likelihood of Harmony Moller’s death as the product would have contained less 7-OH and would have been characterized as reasonably expected to be safe. Exhibit 55.

Harmony Moller's death shows that the risks associated with OPMS kratom as designed far outweigh the burden of instead marketing pure kratom leaf or an unadulterated design that is reasonably expected to be safe per the FDA. In fact, meeting the "burden" of switching designs would only benefit the Defendants, by moving their activities within the law. On the unusual facts the Plaintiff has presented, there can be no genuine question that OPMS kratom is adulterated, being sold unlawfully, and thereby incapable of establishing any utility that would justify the risks it poses to consumers. OPMS kratom products have an unreasonably dangerous design as a matter of law.

VII. ALTERNATIVE ARGUMENT FOR A DECLARATION AND ORDER FINDING CERTAIN FACTS ESTABLISHED IN THIS CASE.

Should the Court decide that any material fact issues still exist that preclude rendering summary judgment on the issue of unreasonable dangerousness for inadequate warning or for dangerous design, the Plaintiff moves the Court to enter a judgment declaring that OPMS kratom products and OPMS Silver Green Vein Maeng Da are adulterated and misbranded under federal law. The Plaintiff also asks the Court to adopt an order under Rule 56(g), recognizing the underlying facts relating to the issues of inadequate warning and dangerous design, as to which the Plaintiff has shown there is no genuine issue of material fact, are conclusive. Such an order will narrow the questions for trial in this case, and for the jury, the parties and the Court, thereby ensuring a more efficient resolution. A list of proposed findings is provided in the motion proper, all relating to facts the Plaintiff has established in its summary judgment proof.

A. This Court Should Declare OPMS Kratom Products, Including OPMS Silver Green Vein Maeng Da, Adulterated and Misbranded as a Matter of Federal Law.

The evidence and argument as to the adulterated and misbranded nature of OPMS kratom are detailed in Parts VI.B.3.b and VI.C.2.b.i, *supra*, and are hereby incorporated into the Plaintiff's

argument for alternative relief. Upon the filing of an appropriate pleading, such as this alternative motion, the Court “may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree.... 28 U.S.C.A. § 2201. Further, Federal Rule of Civil Procedure 54(c) provides that a “final judgment should grant the relief to which each party is entitled, even if the party has not demanded that relief in its pleadings.”

The Plaintiff therefore seeks a judicial declaration that “OPMS kratom products, including Green Vein Maeng Da, are adulterated under § 402(f)(1)(B) of the Food, Drug and Cosmetics Act [21 U.S.C. 342(f)(1)(B)], because they contain a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. They may not be lawfully sold for human consumption.”

The Plaintiff further seeks a judicial declaration that “OPMS kratom products, including OPMS Silver Green Vein Maeng Da, are misbranded under §§ 352(a),(f)(1),(i),(o), and 343(e) & (y) of the FDCA because its labeling is false and misleading, and does not bear adequate directions for use, or adequate warnings. They may not be lawfully sold for human consumption.”

The fact that kratom is an NDI, marketed for drug purposes, and which has not received the required FDA approvals for use as a drug or in a dietary supplement, are not controvertible. The Plaintiff’s alternative motion requests the Court to recognize those facts, and others, in an order pursuant to Fed. R. Civ. P. 56(g). To the extent that recognizing the adulterated and misbranded nature of the OPMS products are legal conclusions rather than facts, however, declaratory relief is appropriate instead. Establishing that OPMS kratom has no right to offer its products for human consumption would be an important declaration of the OPMS Defendants’

rights and duties under the law. Should the Court find that a fact issue remains as to whether the Defendants are offering OPMS kratom products for human consumption, a declaration that such offer would be unlawful will allow the parties to focus on whether that is intended use, rather than disputing the product's legal status.

B. This Court Should Issue an Order Finding That Facts as to Which no Genuine Question Exists are Established by the Plaintiff in this Case.

“If the court does not grant all the relief requested by the motion, it may enter an order stating any material fact—including an item of damages or other relief—that is not genuinely in dispute and treating the fact as established in the case.” Fed. R. Civ. P. 56(g). The Plaintiff believes its proof shows an absence of dispute over several material factual questions, including, *e.g.*: the dangerous characteristics present in OPMS kratom; the fact it contains an NDI that has not received approval to market for human consumption; the absence of any warning about death from OPMS kratom use; and the existence of safer design alternatives at the time the product in this case left Defendants' control.

If the Court should find that there is a factual question that precludes awarding partial summary judgment to the Plaintiff on OPMS kratom's unreasonably dangerous nature for inadequate warning or for unreasonably dangerous design under the LPLA, the Plaintiff asks the Court to recognize the facts that have been established in an appropriate order under Rule 56(g). Doing so will narrow the issues and reduce the time required at trial and aid the parties and court in preparation and management of the case.

VIII. CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that the Court grant its Motion for Partial Summary Judgment, finding that OPMS kratom products and Green Vein Maeng Da are unreasonably dangerous under the Louisiana Product Liability Act for providing an inadequate

warning and for their unreasonably dangerous design. In the alternative, Plaintiff respectfully requests that the Court enter a judgment declaring the adulterated and misbranded nature of these products, and an order recognizing as established in this case those facts that the Plaintiff has shown and as to which no genuine issue of material fact exists.

Respectfully submitted,

/s/ Michael Cowgill

MICHAEL J. COWGILL (FL Bar # 1010945)

Pro Hac Vice

TAMARA J. SPIRES (FL Bar # 127625)

Pro Hac Vice

MCTLAW

1515 Ringling Blvd., Suite 700

Sarasota, Florida 34236

Telephone 888.952.5242

mcowgill@mctlaw.com

tspires@mctlaw.com

-and-

WAGAR HICKMAN, LLC

NELSON W. WAGAR, III (No. 13136)

SARAH WAGAR HICKMAN (No. 35823)

JENNIFER SEILER AVALLONE (No. 35613)

1401 West Causeway Approach

Mandeville, Louisiana 70471

Telephone (985) 888-8740

cwagar@wagarhickman.com

shickman@wagarhickman.com

javallone@wagarhickman.com

Attorneys for Plaintiff, Kathleen Moller