

EXHIBIT 31

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

KATHLEEN MOLLER

*** CIVIL ACTION NO. 24-0228-WBV-DPC**

VERSUS

*** JUDGE WENDY B. VITTER**

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MARTIAN SALES, INC; JOPEN, LLC, a Texas limited liability company; JOHNSON FOODS, 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; ABC INSURANCE COMPANY and John Does 1-4.

* MAGISTRATE DONNA PHILLIPS
* CURRAULT

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EXPERT REPORT OF EVELYN CADMAN
REGARDING HARMONY MOLLER

I. ASSIGNMENT AND RESERVATION

I have been asked to provide expert opinions, on behalf of Plaintiff, Kathleen Moller, regarding the wrongful death of Harmony Moller. This report opines on Defendants' OPMS kratom products, including evaluation of Defendants' product labeling, marketing representations, and kratom's status under the industry standards that govern dietary ingredients and supplements in the United States.

I reserve the right to rephrase or alter my opinions as additional information is received. I reserve the right to supplement this report when further data, documents, or information becomes available and/or to correct it if errors are discovered. Further, at trial, I may use visual aids or demonstrative exhibits, such as diagrams, images, slides, or charts that illustrate and/or explain my opinions.

II. QUALIFICATIONS

I am the Principal Consultant of FDA Compliance Simplified, and I am an expert in product development and regulatory compliance for the food, dietary supplement, cosmetic, and pharmaceutical industries. I provide product development, regulatory compliance and labeling services for FDA and USDA regulated consumer products, including but not limited to dietary ingredients, dietary supplements, food, cosmetics, and over the counter medicines.

At FDA Compliance Simplified, I regularly provide guidance to businesses on the industry and regulatory standards that must be followed to manufacture, market, and/or sell dietary supplements to consumers in the United States. As a part of those responsibilities, I review and rely upon the customary sources of information that establish the standards in our industry for the labeling and marketing of supplements, as well as the prohibited practices that result in regulatory violations, enforcement actions, and prosecutions. The guidance relied upon for these standards includes but is not limited to the publication of regulatory guidance in the Code of Federal Regulations (CFR); official guidance from the FDA issued pursuant to its responsibilities in enforcing the FDCA / DSHEA, such as Import Alerts, Warning Letters, and New Dietary Ingredient Notification (NDIN) Response Letters; formal enforcement actions and prosecutions by the FDA and DOJ (and related court orders) involving supplements; and industry press releases, publications, and conferences. My CV is attached hereto as **Exhibit A**.

III. REVIEW AND SYNOPSIS OF OPINIONS

- a. Kratom is a New Dietary Ingredient (NDI) for purposes of the Dietary Supplement and Health Education Act of 1994.
- b. Defendants did not file a premarket NDI Notification and OPMS kratom is therefore deemed adulterated.
- c. Defendants' OPMS kratom branded products were misbranded, were sold for therapeutic purposes, and sold as unapproved new drugs.

IV. BACKGROUND MATERIALS REVIEWED AND/OR RELIED UPON¹

- a. Plaintiff's Third Amended Complaint for Wrongful Death and Demand for Jury Trial
- b. FDA Import Alert 54-15
- c. FDA Import Alert 66-41
- d. FDA Import Alert 99-45
- e. New Dietary Ingredient Denial Letters:
 - i. FDA letter to American Botanicals Corporation, dated Nov. 5, 2021
 - ii. FDA letter to BD Botanicals Ltd., dated October 25, 2019
 - iii. FDA letter to INI Botanicals, dated Dec. 20, 2016
 - iv. FDA letter to Mr. Luke Dodd, dated Sep. 22, 2015
- f. United States v. 577 Cartons, CV 14-6729 PA, (9th Cir. 2014)
- g. FDA Warning Letters:
 - i. Warning letter to Amafruits, LLC, dated July 21, 2017
 - ii. Warning letter to For Earth, Inc., dated Aug. 19, 2011
 - iii. Warning letter to Tennessee Scientific, Inc./Scientific Formulations LLC, dated Feb. 1, 2011

¹ This is not a complete recitation of all materials I may have access to or reviewed in relation to kratom and/or this matter and I reserve the right to refer to, rely on, or supplement this listing.

- iv. Warning letter to ZEO Health Ltd., dated Jun. 29, 2007
- v. Warning letter to USApeptide.com, dated February 26, 2025
- vi. Warning letter to Umbrella, dated May 18, 2021
- vii. Warning letter to Top Health Manufacturing, LLC, dated June 3, 2024
- viii. Warning letter to Sunshine Trading Company, Inc. d/b/a Nova Tea and Nova Kratom, dated July 3, 2023
- ix. Warning letter to Omni Consumer Products, LLC d/b/a YoKratom, dated June 30, 2022
- x. Warning letter to Market America, Inc., dated February 12, 2020
- xi. Warning letter to KratomNC, dated May 16, 2019
- xii. Warning letter to Kratom Exchange, dated June 30, 2022
- xiii. Warning letter to Klarity Kratom, dated June 30, 2022
- xiv. Warning letter to Herbsens Botanicals, dated June 30, 2022
- xv. Warning letter to Cali Botanicals, LLC, dated June 11, 2019
- xvi. Warning letter to BHP Holdings, Inc., d/b/a BioPure Healing Products, dated June 17, 2020
- xvii. Warning letter to Xcel Research, LLC, dated December 10, 2024
- xviii. Warning letter to Formulife, Inc., Purus Labs, Inc. d/b/a Dark Cyde Supplements, dated January 18, 2012
- xix. Warning letter to Big Easy Confections, LLC, dated August 14, 2014
- h. Photos of the kratom packages discovered near Harmony Moller at the time of her death (MOLLER_000023-000026)
- i. Excerpts of the OPMSkratom.com website, including disclaimers
 - i. See e.g. DEF_MOLLER_007245-007249
- j. FDA and Kratom webpage accessible at: <https://www.fda.gov/news->

[events/public-health-focus/fda-and-kratom](#) (last accessed November 13, 2025)

- k. New Dietary Ingredient Notification for NPI-001, A Dried Kratom Leaf Powder, dated October 21, 2022
- l. Expert Report of Jack E. Henningfield, Ph.D. in *Estate of Dustin Hernandez v. "OPMS WHOLESALE" et al.*
- m. Depositions of:
 - i. 30(b)(6) of Martian Sales, Inc., dated October 28, 2024 & October 29, 2024
 - ii. Deposition of Jack Henningfield, Ph.D. dated February 13, 2025
 - iii. 30(b)(6) of JOPEN, LLC, dated March 14, 2025 (McKibban)
 - iv. 30(b)(6) of Martian Sales, Inc., dated October 8, 2025
 - v. Deposition of Mark Reilly, dated October 8, 2025
 - vi. Deposition of Peyton Palaio, dated October 9, 2025
 - vii. Deposition of Mark Jennings, dated October 9, 2025
 - viii. 30(b)(6) of Calibre Manufacturing, LLC, dated October 10, 2025
 - ix. 30(b)(6) of Nuza, LLC, dated October 10, 2025
 - x. 30(b)(6) of Jopen, LLC, dated October 16, 2025
- n. August 2, 2024, E-mail from Seth Heller to Gwendolyn Payton and Benjamin England
- o. Ou, Oliver, et al., *Kratom Related Adverse Event Reports from the FDA CFSAN Adverse Event Reporting System (CAERS)*, 2021.
- p. Documents related to *Aidan Vidrine et al. v. Konolabs et al.*, Civil Action No. 6:22-CV-00491-SMH-CBW (U.S District Court for the Western District of Louisiana):
 - i. Memorandum in support of motion for extension of time to effect service, and exhibits thereto
 - ii. Memorandum in support of third motion for extension of time

to effect service

iii. Order dismissing matter without prejudice

q. Confidential documents produced in discovery including but not limited to:

i. DEF_MOLLER_004701-004707

ii. DEF_MOLLER_007305-007306

iii. DEF_MOLLER_007307-007308

iv. DEF_MOLLER_007309-007310

v. DEF_MOLLER_007311-007312

vi. DEF_MOLLER_007313-007314

vii. DEF_MOLLER_007462-007465

viii. DEF_MOLLER_007466-007469

ix. DEF_MOLLER_007470-007473

x. DEF_MOLLER_007474-007477

xi. DEF_MOLLER_007478-007481

Any of the above noted material may be used as exhibits to summarize or support my opinions herein. I reserve the right to supplement my disclosures based on the parties' continuing development of information through deposition and discovery.

V. OPINIONS AND BASIS THEREOF

It is my opinion that the supply, marketing, distribution, and sale of OPMS Kratom fails to comply with basic industry and regulatory standards of care for supplements, and in particular New Dietary Ingredients (NDI). The Kratom at issue in this case was misbranded under the industry and regulatory standards that

govern health claims, labeling, and branding for dietary ingredients and supplements. Defendants violated the standards that prohibit the marketing, distribution, and sale of unapproved and new drugs. My testimony and the conclusions reached in this report are and will be based on my education, training, and experience.

A. OPMS Kratom: A New Dietary Ingredient Not Safe for Human Consumption.

In the supplement industry, any entity looking to sell an ingredient or supplement for human consumption should first become familiar with the standards that govern the substance that is proposed for sale, including any agency guidance provided on the status of that substance. Kratom is a “New Dietary Ingredient” (NDI) for purposes of the Dietary Supplement Health and Education Act of 1994 (DSHEA). The FDA’s classification of kratom as an NDI is based upon the definitions established by Congress in DSHEA and is well publicized. See, for example, Import Alert 54-15 (FDA, 04/08/2021). The FDA has already established that kratom is an NDI. According to the publicly available Import Alert, to the best of the FDA’s knowledge, there is no information demonstrating that this substance was marketed as a dietary ingredient in the United States before October 15, 1994. See, Import Alert 54-15; see also, FDA letter to American Botanicals Corporation, dated Nov. 5, 2021.

Because kratom is an NDI, any manufacturer or distributor proposing to sell kratom for human consumption should first familiarize themselves with the industry practices and standards that are necessary to confirm that the product is

reasonably expected to be safe. This standard of due diligence is also necessary for the premarket “NDI Notification” which must be submitted to the FDA at least 75 days before kratom can be introduced or delivered for introduction into interstate commerce. Under this standard, the entity must substantiate a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will be reasonably be expected to be safe. If the required premarket NDI Notification does not acceptably demonstrate appropriate safety, then any dietary supplement product containing kratom is classified as an adulterated product, and not appropriate for sale to consumers because its safety has not been established.

Based on the information provided, none of the named defendants ever verified that the OPMS kratom products manufactured and sold by them were reasonably safe for human consumption, either before or after they were marketed. FDA Response Letters to NDI Notifications pertaining to kratom uniformly confirm that the safety of kratom and its derivatives has not been established, and these products are not reasonably expected to be safe. Publicly available information from the FDA and elsewhere identify serious concerns regarding the toxicity of kratom in multiple organ systems, with risks to humans that include the risk of death. Even Dr. Henningfield, who has worked directly with Mr. Peyton Palaio regarding kratom, testified that it was in the public interest for the OPMS product line to meet the safety standards required for an acceptable NDIN. See, Henningfield Dep. at pp.86 & 96-97. It is a clear violation of industry standard for any manufacturer or

distributor to sell a product for human consumption that has been publicly declared by the FDA to be adulterated because of inadequate information regarding its safety for consumers.

B. OPMS Kratom: Misbranded and Sold as an Unapproved, New Drug.

In addition to being an adulterated NDI, OPMS Kratom was misbranded and sold as an unapproved new drug, without adequate warnings. Kratom, kratom-containing dietary supplements, and bulk dietary ingredients are subject to important industry standards and regulations that prohibit the sale of products that are “misbranded”, “drugs”, and/or “new drugs”. See, e.g., 21 CFR § 101.93(f) and (g). These standards focus on the intended use of the products; the labeling, marketing, and/or promotion of such products; and the types of claims made about the products. These standards have been the subject of well publicized enforcement actions by the DOJ, including a Final Debarment Order and federal court decrees. See, *Matthew Dailey: Final Debarment Order*, FDA-2019-N-3310, Federal Register Vol. 85, No. 52, page 15193-4 (March 17, 2020); US DOJ Press Release: *Michigan Man Sentenced for Unlawfully Importing and Distributing Misbranded Drugs* (May 8, 2019); US DOJ Press Release: *North Carolina Man Ran Lucrative Fraud Scheme Selling Unapproved Substances that Mimic the Health Benefits of Legal Drugs* (August 31, 2021); Consent Decree of Condemnation, Destruction, and Permanent Injunction, *United States v. 577 Cartons*, CV 14-5729 PA (MRWx) (U.S.D.C., CA C.D., W.D., Dec. 1, 2014); Consent Decree of Condemnation and Destruction, *USA vs. Defendant Articles* (USDC FL, October 26, 2021); *FDA*

Announces Seizure of Adulterated Dietary Supplements Containing Kratom (FDA News Release, and federal order, dated October 26, 2021); see also, FDA and Kratom (<https://www.fda.gov/news-events/public-health-focus/fda-and-kratom>) and FDA Warns Consumers Not to Use OPMS Black Liquid Kratom (July 26, 2024; <https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-not-use-optimized-plant-mediated-solutions-opms-black-liquid-kratom>).

1. Kratom should not be sold as a drug.

This standard is violated when kratom is sold for the purpose of treating and mitigating diseases, including but not limited to addiction, and to otherwise affect the structure and function of the human body. Knowingly selling kratom for its drug effects is also improper. For years, FDA Warning Letters have been publicly available as industry guidance, reinforcing the obligation to avoid selling kratom as a drug or otherwise. See, for example, DHHS NDIN Response Letter re: Luke Dodd, “Atomic K” (September 22, 2015); FDA warning letter to “Cali Botanicals, LLC” (Warning Letter 57320, June 11, 2019).

2. Kratom should not be sold as a “new drug”.

The FDA Warning letters also address the industry standard against the sale of kratom as a “new drug”. The standard prohibiting sale of unapproved “new drugs” is violated when kratom, which it is not generally recognized as safe and effective, and for which it has not been approved based on scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective, is sold for human consumption under the direction of a healthcare professional. See, 21 U.S.C. § 321

(p). The requirement that kratom first be approved by the FDA before it is sold as a new drug is designed to ensure the health and safety of consumers, like Harmony Moller. According to industry guidance, there are currently no FDA-approved kratom drug products.

3. Kratom should not be sold as a “misbranded” drug or sold without adequate directions for use.

A kratom product is “misbranded” when: (1) it is knowingly sold for use as a drug but fails to bear adequate directions for its intended uses; and/or (2) it is knowingly offered for conditions that are not amenable to self-diagnosis and treatment by persons who are not medical practitioners. In such cases, adequate directions for the intended uses cannot be written to allow safe use by the ordinary consumer. See, 21 USC § 352(f)(1); 352(a), (f), (i), (o) (identifying misbranded drugs); see also, FDA Warning letter to Umbrella (May 18, 2021). The Consumer Product Safety Commission notes that consumers will assume a product is safe based on the labeling. It is a violation of the industry standard to sell kratom intended for use as a drug, without labeling bearing adequate directions for use, warnings and cautions for safe use, and other “material information” necessary for proper use of the product. 21 CFR § 1.21; 21 CFR § 101.9(k) (labeling a supplement as effective in regard to a disease or symptom is misbranding); and 21 CFR § 201.5 (adequate directions for use defined); 21 CFR § 352(a), (f), (i), (o) (misbranding via false and misleading labels).

The OPMS Kratom products at issue were sold in violation of these standards. The OPMS defendants have 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. October 16, 2025, Deposition of JOpen, LLC at pp.65:15-66:15; March 14, 2025, Deposition of JOpen, LLC (Rachel McKibban v JOpen, LLC, et al.) at pp. 159:18-23 and pp.160:19-161:2; October 28, 2024, Deposition of Martian Sales at pp.206:23-207:10; October 9, 2025, Deposition of Peyton Palaio at pp.44:11-45:19. This is a direct violation of consumer safety standards. FDA News Release, *FDA warns companies selling illegal, unapproved kratom products marketed for opioid cessation, pain treatment and other uses* (May 22, 2018). Defendants knew since at least 2012 and know today that OPMS consumers were and are using OPMS kratom for that purpose despite labels indicating it was only for use as a “botanical specimen”. *Id.* Despite published research documenting toxic levels and adverse events, there is no specific guidance as to safe use or dosing. Papsun, D., Schroeder, W., Brower, J. et al. *Forensic Implications of Kratom: Kratom Toxicity, Correlation with Mitragynine Concentrations, and Polypharmacy*. Curr Addict Rep 10, 272–281 (2023) (<https://doi.org/10.1007/s40429-023-00477-4>). The warning on the OPMS kratom packages say nothing about seizure, cardiorespiratory adverse effects, or death but is instead a caution for those who “**ARE PREGNANT, PLAN TO BECOME PREGNANT, OR WHILE BREASTFEEDING**”. A properly prepared NDIN would have needed to address and warn about these basic issues of human safety, such as maximum safe dose, and risks of addiction, seizure, cardiorespiratory adverse effects, and death.

C. OPMS Was Improperly Sold For Medical Purposes.

Kratom containing products must not be promoted or sold for health and medically related purposes, without first complying with the safeguards, procedures, and approvals for promoting such products for medicinal or drug purposes. Yet, the facts of this case show that OPMS Kratom products were sold for those purposes. Despite recognizing that these products were not to be marketed as a substitute for medical treatment, Mr. Gabbay, Mr. Reilly, and Mr. Palaio, individually and through their corporate entities intended that the products be sold for that very purpose and knew that OPMS consumers were in fact using it for that purpose. October 16, 2025, Deposition of JOpen, LLC at pp.65:15-66:15; October 28, 2024, Deposition of Martian Sales at pp.206:23-207:10; October 9, 2025, Deposition of Peyton Palaio at pp. 44:11-45:19.

OPMS kratom consumers, including Harmony Moller, were not properly warned of the serious risks from Kratom, including the risks of seizures, cardiorespiratory adverse effects, death, dependence and addiction, and drug-drug interactions. These risks are identified in FDA guidance and the related peer-reviewed scientific and medical literature. See, e.g., Xiaotong Li, et al, *An evaluation of adverse drug reactions and outcomes attributed to kratom in the US FDAERS system 2004 to 2021* (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10264943/>). The OPMS kratom warning that it is “only for use as a botanical specimen” is disingenuous at best. This does not make the product legal and does not allow a business to avoid the testing and approvals necessary to ensure that products containing kratom are safe for human consumption before they are put on the shelf.

Similarly, a general statement that the “organic” product “can be dangerous” with a directive to consult with a healthcare professional on “how to use it safely”, is incomplete and deceptive. Healthcare professionals are frequently unfamiliar with non-prescription botanicals like kratom. And it is false to suggest that medical professionals will instruct on the “safe” use of a OPMS product that was never verified as safe for human consumption in the first place. This generic warning is also incomplete and deceptive in failing to communicate the severe nature of the dangers documented for kratom, which includes the risk of seizure, cardiorespiratory adverse effects, addiction, and death.

The OPMS labeling does not provide directions for use that might have mitigated these serious risks. There is no maximum safe dose specified, or any dose at all. There is no indication that a maximum safe dose has ever been established for OPMS kratom via NDIN, or any other process. These violations of industry and regulatory standards related to warnings and directions are very serious, as Kratom consumers may forego necessary medical treatments and supervision without any information to guide them in the safe use of a product improperly sold as an alternative to medical care.

D. OPMS Labeling Failed To Identify The Entity Responsible For The Product, Rendering OPMS Kratom Misbranded.

Name and Place of Business. The OPMS label is deemed misbranded because it does not correctly identify the actual name and place of business for the entity responsible for the product. FDA Guidance, at Q&A No. 1, citing Section 403(e) of the FD&C Act (21 U.S.C. § 343(e)); see also, Warning Letter to Big Easy

Confections, LLC, dated August 14, 2014. The label shall include the name and place of business, including the city, state, and zip code unless the address is listed in a current city directory or telephone directory. 21 CFR § 101.5(d). The OPMS label identifies Choice Organics, and provides a phone number, address, and email. However, 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. Not to mention, the information simply does not accurately or honestly identify the entity or entities responsible for OPMS kratom. See Exhibit 1 and Exhibit 42 to Plaintiff's Memorandum in Support of Motion for Partial Summary Judgment (Dkt. No. 132). Mr. Gabbay testified that he was familiar with this requirement, and that he was previously informed that his kratom products were being destroyed for the failure to disclose such information. However, rather than provide an honest disclosure, Mr. Gabbay's response was to invent names for businesses that did not exist ("Choice Organics" for OPMS and "KonoLabs" for Whole Herbs), and identify California post office boxes as the place of business, even though an actual street address is to be included and no business is conducted in those locations. March 14, 2025, Deposition of JOpen, LLC (*Rachel McKibban v JOpen, LLC, et al.*) at pp.66:8-68:24, pp.79:19-81:3, pp.212:15-213:5, pp.219:17-220:4, & pp.239:24-240:20. This deceptive marketing ploy, including the listing of Choice Organics on the OPMS kratom website, is inconsistent with the basic standards for transparency about who is responsible for

products consumed by humans. The marketing ploy is likely to mislead many consumers.

Adverse Event Reporting. As with the fictional OPMS labeling, the adverse event reporting system for OPMS kratom presents a disturbing lack of regard for the industry standards and human safety. The FDA’s labeling guidance, which is based on federal law, makes clear that the label must enable consumers to report serious adverse events to the actual place of business, via the domestic address or phone number. FDA Guidance for Industry: Q&A Regarding Labeling of Dietary Supplements (Federal Register Vol. 74, No. 168, p. 45221; Docket Number FDA-2007-D-0209; September 2009); see for example, Warning Letter to Big Easy Confections, LLC, dated August 14, 2014.

The OPMS label is deemed misbranded because it does not specify a complete domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event. FDA Guidance, at Q&A No. 1, citing Section 403(y) of the FD&C Act (21 U.S.C. § 343(y)). This is a basic directive to provide “all information necessary to enable a serious adverse event report to reach the responsible person.” *Id.* The FDA also recommends “a clear, prominent statement” informing consumers that they may report serious adverse events via the address or phone. *Id.* Q&A No. 2.

The FDA guidance also emphasizes that the responsible person must use product labeling that includes information on how to report an adverse event, must maintain an established system for collecting adverse event reports, and must

submit serious adverse event reports to FDA no later than 15 business days after a report is received. 21 USC § 379aa-1(c)(1)-(2); see FDA Warning Letter to Market America Inc. (MARCS-CMS 588959 – Feb. 12, 2020) (warning for failure to report adverse events); FDA Warning Letter to BHP Holdings Inc., dba BioPure Healing Products (MARCS-CMS 597687 – June 17, 2020) (manufacturer improperly rejected adverse event complaints as “invalid” without proper investigation and assessment of product safety risk).

Prompt submission of serious adverse event reports is important for public health reasons. A properly functioning adverse event reporting system is an important feature of product and consumer safety. Both the FDA and the manufacturer must be aware of the extent to which a particular product may be harming or killing consumers. The information identifies dangers and trends and allows those responsible to prevent future harms through recalls, enforcement actions, improved design and warnings, or other actions.

Notwithstanding the importance of effective adverse event reporting, Defendants did not have a set of procedures in place for assessing the seriousness of an adverse report, gathering the necessary information, and ensuring it is properly handled until approximately early 2025. October 16, 2025, Deposition of JOpen, LLC at pp.34:22-36:3, pp.76:25-77:22, pp.124:17-128:2, & pp.159:13-159:23; October 28, 2024, Deposition of Martian Sales, Inc. at pp.119:3-120:13 & pp.258:23-259:1-5. See, FDA Human Foods - Guidance Document, *Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for*

Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (FDA-2007-D-0372; September 2013). The person responsible for handling the adverse event must be competent for the job and must follow up with the reporter and actively seek the minimum data elements needed to inform the FDA about the adverse event. The responsible person must also keep records related to any adverse event report for six years, regardless of whether the event was reported to FDA. 21 USC § 379aa-1(e)(1).

Prior to working with Pratt in early 2025, Jopen was the entity responsible for adverse event reporting for the entire chain of commerce for OPMS kratom. October 16, 2025, Deposition of JOpen, LLC at pp.34:22-35:22. To the extent that Jopen has ever had a “responsible person” for adverse events, which appears to have been Mr. Gabbay, it does not appear that any responsible handling or preservation of adverse event records took place. The descriptions have been vague and inconsistent, and unverified with records or documentation. There is conflicting testimony about where and how the reports are being handled. October 28, 2024, Deposition of Martian Sales, Inc. at pp.119:3-120:13 & pp.258:23-259:1-55; October 16, 2025, Deposition of JOpen, LLC at pp.47:12-23, pp.76:25-77:22, pp.124:17-128:2, & pp.159:13-23. The lengthy email exchange between the FDA’s Seth Heller and Benjamin England regarding “OPMS Black Liquid Gold” reveals a shocking failure in the adverse event reporting system, as well as a lack of transparency or cooperation with the public officials attempting for months to receive a response regarding a kratom related death, involving a 35-year-old-male

with a January 15, 2024 autopsy report determining that the cause of death was accidental acute Mitragynine intoxication. October 16, 2025, Deposition of JOpen, LLC at pp.76:25-77:22. Mr. Gabbay's suggestion that the death was an anonymous or false report generated by a competitor cannot be squared with the FDA's specifics regarding the autopsy in their possession.

In this case, it is apparent that reports of serious adverse events, including deaths, related to OPMS are being mishandled, ignored, or destroyed. See, October 16, 2025, Deposition of JOpen, LLC at pp.34:22-36:3, pp.76:25-77:22, pp.124:17-128:2, pp.159:13-159:23, pp.215:25-216:18, & pp. 217:22-218:22; see also, August 2, 2024 email from Seth Heller to Benjamin England & Gwendolyn Payton; Filings from *Estate of Vidrine* and *Estate of Paul*. To this date Defendants indicate that these death reports do not exist. October 16, 2025, Deposition of JOpen, LLC at pp.47:9-47:23 & pp.126:19-127:3 (reporting no adverse events prior to hiring Pratt); see also, October 9, 2025, Deposition of Mark Jennings at pp.53:21-54:1 (states he has not seen any death certificates associating a death to kratom). Jopen indicates that it recently sourced out its duty to John Pratt LLC. Yet, Jopen suggests that Pratt has discretion to receive reports of product related deaths without any notification to the distributor, manufacturer, or the FDA. October 16, 2025, Deposition of JOpen, LLC at pp.185:4-185:24.

There is no clear indication that an actual system for adverse event reporting has ever operated for OPMS products. To the extent that it has, it is

clearly inadequate and ineffective in fulfilling the important mandatory standards for the handling of adverse events.

Kratom Is Not a Food. I understand that those responsible for OPMS may claim that they may disregard the foregoing safety standards because kratom is a “food”. Based on my review, OPMS was never intended to be sold as a “food” and cannot be credibly identified as a “food”. See, 21 U.S.C. § 321(ff)(2)(B) (supplements should not be represented for use as a conventional food or as a sole item of a meal or the diet); FDA – *Questions and Answers on Dietary Supplements* (2/21/24) (<https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements>). A theory that OPMS is a “food” is contradicted by the labeling, the intended use, and the way the product has been designed, marketed, and distributed. There is no statement of identity to credibly suggest that OPMS is a food. Food products generally do not direct the consumer to inform their physician of the “alkaloid content” of the material before consuming it. Food product labels do not instruct a consumer that the leafy material is to be used as a “botanical specimen”.

Even if a kratom product were characterized and labeled as “food”, it would still need to be safe for human consumption. In fact, the safety standard for food ingredients places a higher burden on the industry than the standard for dietary ingredients in supplements. See, FDA – *How U.S. FDA’s GRAS Notification Program Works* (2/9/18) (<https://www.fda.gov/food/generally-recognized-safe-gras/how-us-fdas-gras-notification-program-works>). The GRAS standard

requires demonstration of a reasonable certainty of no harm, as opposed to the reasonable expectation of safety that must be documented through the NDIN process. Even an agricultural food product needs to be safe for its intended use when put on the market. There is no evidence that American consumers are sitting down for a bowl of kratom as a meal or otherwise consuming the kratom as a food.

E. OPMS Was Not Properly Tested

Defendants claim that OPMS products are tested for safety, purity, and potency (i.e. the level of kratom alkaloids present). Nonetheless, OPMS' testing is wholly deficient. Martian Sales has provided manufacturers such as Nuza and Calibre with a specification sheet used for OPMS kratom products. See e.g., DEF_MOLLER_004701-004707. However, the specification sheet has no specification for the Green Vein Maeng Da powder product at issue in this case. The specification for the Green Vein Maeng Da capsule further does not provide a specification for the level of mitragynine or other alkaloids to be contained in the finished product. Yet, testing documents produced in discovery, which are allegedly related to the products at issue², include multiple alkaloids not listed on the spec sheet. See e.g., DEF_MOLLER_007305-007314 & DEF_MOLLER_007462-007481. Further, the tests state that the alkaloid level results are simply reported to the manufacturer or party ordering the testing, and do not indicate a pass or fail. *Id.* This creates a circular loop that fails to corroborate the actual specification and

² I have not been provided with corroborative documentation illustrating that the produced testing documents in fact relate to the products at issue and it is my understanding no such documents have been produced.

whether the products contain alkaloids at levels more likely to cause adverse events because though the results are reported, there is in fact no specification against which to compare the test results. October 16, 2025, Deposition of JOpen, LLC at pp.49:3-25; pp.131:2-17; pp.134:6-135:24; & pp.156:5-157:23; October 10, 2025, Deposition of Nuza, LLC at pp.62:19-68:25; pp.69:21-71:8; pp.73:8-17; & October 10, 2025, Deposition of Calibre Manufacturing, LLC at pp.17:19-18:11; pp.24:5-25:25; pp.27:6-24; & pp.97:25-100:21. Based upon the testimony and documents produced, there is an ineffective testing scheme for the OPMS kratom products at issue which only raises further safety concerns.

F. OPMS Was And Is Not Fit For The Shelf.

The kratom in the OPMS products at issue were imported in violation of import alerts without any premarket verification of safety, sold as an unapproved, adulterated and misbranded drugs that were not fit for human consumption. They should not have been on the shelf. As a consultant for the standards governing the sale of FDA regulated ingredients and products, the OPMS defendants' acknowledgement that their own products are not deemed fit for human consumption is alarming. March 14, 2025, Deposition of JOpen, LLC (*Rachel McKibban v JOpen, LLC, et al.*) at pp.264:20-23 & pp. 267:10-12; and October 16, 2025, Deposition of JOpen, LLC at pp. 13-25 & pp.55:10-56:14. Simply marking a kratom product as a "botanical specimen" and then putting it on the shelf as if it is safe for human consumption, does not make the sale of that product compliant with the industry standards, and does not excuse the OPMS companies from their

responsibility to first ensure that products containing kratom are safe for human consumption before they are put on the shelf. The products at issue were sold without the important instructions for use, dosing information, proper testing, and warnings necessary to alert consumers to the risks of the actual serious adverse events associated with kratom, which includes addiction, seizure, cardiorespiratory adverse effects, and death.

In the exercise of reasonable care, Defendants should have complied with the regulatory scheme applicable to OPMS kratom and described herein. Had Defendants done so, it is *more probable than not* that ordinary, reasonable consumers would have altered their behavior—by not purchasing the product (if it was in fact appropriately available for sale), not consuming the product, or changing their behavior in a way to mitigate risk and thereby have *avoided injury or death*. The burden of compliance with the applicable regulatory scheme would have been minimal compared to the magnitude and likelihood of the harm.

VI. BIAS, COMPENSATION, AND PAST EXPERT TESTIMONY

I have no conflict of interest that would result in bias. I am being reimbursed through Plaintiff's counsel for the work that I am providing as an expert on an hourly basis. I am not employed by any company that dispenses or promotes the use of kratom. I never met Harmony Moller, nor do I know the Moller family.

My hourly rate for review and report preparation is \$375 per hour in this case, including but not limited to: research, record review, report writing, preparation, telephone consultation, or any other work. The rate for deposition and trial testimony

is \$475 per hour. Travel Time is billed at \$175 per hour with travel expenses reimbursed at actual cost.

During the previous four years, I have testified as an expert at trial or by deposition in the following matters:

1. Coyne v. Society Botanicals et al; (Cowlitz County Superior Court, Kelso, WA); approximate date: July 6, 2023;
2. Taylor v. Mood Rite et al; (Deposition via zoom; approximate date: August 20, 2024.

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Evelyn Cadman

11/17/2025

Dated

EXHIBIT A

EVELYN D. CADMAN
9172 West 92nd Avenue
Westminster, CO 80021
303-432-1605
ECadman@FDASimplified.com

EXPERTISE

Regulatory compliance for a wide range of FDA-regulated products
Preparation of claim substantiation dossiers and FDA notifications for new ingredients
Research and consumer health product development
Nutritional evaluation of food product lines

PROFESSIONAL EXPERIENCE

FDA Compliance Simplified (www.FDASimplified.com), a service of Cadman Consulting Services, LLC;
Westminster, CO
2001 - Present

Scientific & Regulatory Consultant—FDA regulatory affairs services including labeling / marketing reviews and submissions relevant to foods, dietary supplements, cosmetics, OTC drugs and medical devices. Technology reviews for patent potential and consumer product applications. Research and report preparation support. Consultation on regulatory issues regarding consumer product goods litigation.

Boston Market Corporation, Golden, CO

Concurrent with present position June 2005 to September 2007

Nutrition & Labeling Manager— Managed food product labeling process to ensure compliance with FDA, USDA and FTC regulations. Reviewed global regulatory status and consumer perception of proposed food product ingredients. Assisted marketing with program development and menu labeling requirements.

NBTY, Inc., Northglenn, CO

Concurrent with present position April 2002 through November 2004

Nutrition Researcher— Reviewed new products for safety and regulatory compliance. Reviewed literature for claim and safety data. Served as FDA, FTC liaison.

University of Colorado Health Sciences Center, Division of Cancer Prevention & Control.

Concurrent with present position Q1 2002

Professional Research Assistant (temporary contract) for SHINE Women's Health Study—Recruited study participants and assisted lead researchers with case control study of breast cancer.

NatureSmart, a subsidiary of Whole Foods Market, Inc., Thornton, CO

1997 - 2001

Senior Research Scientist (January 1999); Research and Development—Responsible for coordination of research efforts for the corporation's largest direct marketing division including new product formulation, literature research and reporting on nutritional supplements for new and existing products. Managed research efforts of two staff scientists. Additional responsibilities included providing technical assistance for review of patents and FDA regulations, design of in-house efficacy studies and coordination of committee to streamline the new product development process.

Research Scientist (January 1998); Research and Development—Responsible for coordination of research efforts for the corporation's largest direct marketing division including new product formulation, literature research and reporting on nutritional supplements for new and existing products.

Research Specialist (June 1997 - January 1998); Research and Development—Responsible for new product formulation, literature research and reporting on nutritional supplements for new and existing products.

Abbott Laboratories, Abbott Park, IL
1986 - 1996

Pharmacologist; Neuroscience Area, Pharmaceutical Products Division 1990 - 1996
Developed assays and conducted research aimed at hypothesis testing for Alzheimer's Disease projects. Responsible for experimental design, analysis, interpretation and presentation of data in lecture and manuscript formats. Performed literature searches using various computer databases. Coordinated research of summer interns.

Pharmacology Research Associate II 1986 - 1990

Developed functional assays to assess potential pharmacologic agents for Neuroscience drug discovery projects. Assisted development of COGF Oracle database. Developed and presented COGF database training course. Administered COGF database for cognitive function project. Served on divisional safety committee.

EDUCATION

Bachelor of Science in Biophysical Sciences. University of Houston, Texas, May 1980

Summa cum laude

University Honors, Thesis: Purification and characterization of a phospholipase A activity from *Alteromonas espejiana*.

Certified Nutritionist (CN). American Health Science University, Denver, Colorado, May 1999

EXPERT WITNESS EXPERIENCE

Coyne v Society Botanicals, LLC

Case No. 20-2-00874-08, Cowlitz County Superior Court Kelso, Washington, July 2023

Nature of Testimony: FDA regulations and industry standards required prior to marketing a consumer product (kratom).

Taylor et al. v. Mood Rite, LLC et al.

Case No. 22A01635, Dekalb County Georgia, August 2024

Deposition regarding FDA regulations and industry standards required prior to marketing a consumer product (kratom).

INVITED LECTURES

- Panelist for Colorado Food Works program Avoid the Lawsuit – discussion of labeling issues for foods and consumer product good. Cappello's Manufacturing, Arvada, CO, November 15, 2023, <https://www.instagram.com/coloradofoodworks/?hl=en>.
- US FDA Regulations Affecting Food Technology Products, Merage Institute Food Innovation Summit, July 12, 2023.
- National Bioengineered Food Labeling Standard as part of UNPA's Regulatory Education Series Webinar, the UNPA webinar "In the BEginning"... Dietary Supplements Supply Chain Starts with Ag, February 10, 2022, <https://www.youtube.com/watch?v=g6IRLfkdkmE>.
- Importing Foods into the US, Merage Institute Food Innovation Summit, March 20, 2019; March 20, 2018; May 24, 2017; and June 14, 2016, Costa Mesa, CA.
- Understanding the New Facts Panel Regulations, UNPA Expert Insights Webinar, June 21, 2018
- Labeling 101; All Packaging Inc., Aurora, CO April 27, 2017
- Labeling Hot Topics, Naturally Boulder, Boulder, CO March 29, 2017
- Preparing for the New Nutrition Facts Box, Women in Packaging and Manufacturing, September 13, 2016

- FDA and Clinical Herbalism, Colorado School for Clinical Herbalism, October 25, 2019, Lafayette, CO; November 9, 2017, November 11, 2016 and October 22, 2015, Boulder, CO.
- Labeling Matters: Labeling Basics for Widgets, Watches and Waffles, Women in Packaging and Manufacturing, April 14, 2015 & Colorado Specialty Food Makers Group, October 21, 2015, Denver, CO.
- A Way Forward: Challenges and Opportunities with the US FDA: Western Canada Agri-Innovation Boot Camp, October 14 – 19, 2012, Winnipeg, Saskatoon and Vancouver.
- Regulatory Environment & Hurdles: Challenges & Opportunities, Food for Health: Agri-Innovation Conference, February 14, 2012, Canadian Consulate, San Francisco.
- Elevate your Brand: The Label as Table of Contents; Nosco Corollary Lecture; Supply Side West, October 12, 2011, Las Vegas, NV.
- An Introduction to Dietary Supplement Structure Function Claims, Regulatory Affairs Professional Society Annual Conference, October 24 -27, 2010, San Jose, CA.
- Nutritional Genomics and the Future of Food Labeling; Nutritional Genomics Conference; California State Polytechnic University, Pomona, CA, November 12-14, 2009
- Keynote Speaker, Denver Metro Area Chamber of Commerce, Small Business Development Center Awards Reception, May 17, 2002. How to have a Healthy Business—VC Funding

PUBLICATIONS

1. Katrina Emmel, Evelyn Cadman, Cheryl Dicks, NDI Pathway in 2020, Nutritional Outlook, Nutritional Outlook Vol. 23 No. 2, March 2020, pages 2-6.
2. Katrina Emmel, Evelyn Cadman, What is CBD's regulatory status, and how should companies proceed with caution? Leading industry regulatory consultants chime in, Nutritional Outlook, Vol. 22 No. 7, August 2019.
3. Evelyn Cadman, Cosmetics in *Fundamentals of US Regulatory Affairs*, 8th Edition. 2013.
4. Evelyn Cadman, Nutritional Genomics and the Future of Food Labeling in *Nutritional Genomics: The Impact of Dietary Regulation of Gene Function on Human Disease*, Edited by Wayne R. Bidlack and Raymond L. Rodriguez, CRC Press, 2011.
5. Evelyn Cadman, Cosmetics in *Fundamentals of US Regulatory Affairs*, 7th Edition. 2011.
6. Maruthi Prasad Palthu and Evelyn Cadman, Dietary Supplements and Homeopathic Products in *Fundamentals of US Regulatory Affairs*, 7th Edition. July 2011.
7. Evelyn Cadman (ed.) Food Products in *Fundamentals of US Regulatory Affairs*, 7th Edition. July 2011.
8. Kraska, RC., Cadman, ED., McQuate, RS., (2010) Stevia-Derived Sweeteners: Safety, Regulatory & Labeling Considerations, Stevia World Americas, Atlanta, GA.
9. Evelyn Cadman, Cosmetics in *Fundamentals of US Regulatory Affairs*, 6th Edition. August 2009.
10. Maruthi Prasad Palthu and Evelyn Cadman, Dietary Supplements and Homeopathic Products in *Fundamentals of US Regulatory Affairs*, 6th Edition. August 2009.
11. Cadman, E.D. and Puttfarcken, P.S., (1997), β -amyloid peptides initiate the complement cascade without producing a comparable effect on the terminal pathway in vitro, *Experimental Neurology* 146:388-394.
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13. Cadman, E.D., Naugles, D. D. and C.M. Lee, (1994), Cyclic AMP is not involved in Interleukin-1 induced Interleukin-6 Release from Human Astrocytoma Cells, *Neuroscience Letters* 178(N2):251-254.
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Enhancing and Anxiolytic Activities. 1. In-vitro Characterization, *Journal of Pharmacology and Experimental Therapeutics* 270 (N1):310-318.

16. Garvey, D.S., Wasicak, J.T., Elliott, R.L., Lebold, S.A., Hettinger, A.-M., Carrera, G.M., Lin, N.-H., He, Y., Holladay, M.W., Anderson, D.J., Cadman, E.D., Raszkievicz, J.L., Sullivan, J.P. and S.P. Arneric', (1994), Ligands for brain cholinergic channel receptors: Synthesis and in vitro characterization of novel isoxazoles and isothiazoles as bioisosteric replacements for the pyridine ring in nicotine, *Journal of Medicinal Chemistry* 37 (26):4455-4463.
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ABSTRACTS

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2. Cadman, E.D. and C.M. Lee, (1993), Regulation of the Release of Cytokines from Human Astrocytoma Cells, *Neuroscience Abstracts* 19:95.
3. Lin, N.-H., Anderson, D., Cadman, E., Garvey, D. and S.P. Arneric', (1992), Synthesis and evaluation of nicotinic analogs as neuronal nicotine receptor ligands, Abstracts of papers of the American Chemical Society 204 (Aug):76-MEDI.
4. Cadman, E.D. and S.P. Arneric', (1992), Evidence for functional diversity of neuronal nAChRs regulating neurotransmitter release in rat brain, Eighth International Cholinergic Symposium, Montreal.
5. Brioni, J.D., Linville, D.G., Cadman, E.D., Williams, M., Buckley, M., Anderson, D.J. and S.P. Arneric', (1991), Classical nicotinic agonists differentially affect cognition, cortical cerebral blood flow (CBF) and dopamine (DA) release, *Neuroscience Abstracts* 17:1236.
6. Garvey, D.S., Chung, J.Y.-L., Shue, Y.K., Cadman, E., Anderson, D., Arneric', S. and M. Williams, (1991), Novel amino terminally modified derivatives of oxotremorine are more efficacious agonists at cortical muscarinic receptors of the M-1 subtype, *Neuroscience Abstracts* 17:388.

7. Anderson, D.J., Cadman, E., Vella-Rountree, L., Arneric', S.P. and M. Williams, (1990), The aminopyridazine muscarinic agonist, SR 95639A, is a functional M2 receptor antagonist in rat brain, Neuroscience Abstracts 16:1059.
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11. Vickroy, T.W. and E.D. Cadman, (1986), Electrically-induced release of cholecystokinin-like immunoreactive material from slices of rat cerebral cortex, Neuroscience Abstracts 12:825.
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