

Testimony Before the Ohio House Agriculture Committee Regarding House Bill 587

Chair Klopfenstein, Vice Chair Newman, Ranking Member Miller, and members of the Agriculture Committee:

Thank you for the opportunity to provide testimony on House Bill 587.

My name is Jessica Gerding. I reside in Medina County, Ohio. I am a manufacturing consultant and own and operate an ingredient manufacturing facility in Pennsylvania and a dietary supplement manufacturing facility in Florida. My work focuses on botanical standardization, regulatory compliance, and safety evaluation under the federal dietary supplement framework.

I am here to speak from a manufacturing and scientific perspective.

House Bill 587 recognizes that kratom products exist and seeks to regulate them through registration, labeling disclosure, contaminant standards, alkaloid limits, and age restrictions. That reflects an important principle: oversight protects consumers.

Under federal law, kratom is regulated as a dietary supplement. The Dietary Supplement Health and Education Act requires that any dietary ingredient not widely marketed prior to October 15, 1994 be submitted to the FDA through a New Dietary Ingredient notification, or NDI, before interstate sale.

The NDI standard is not zero risk. The legal standard is a “reasonable expectation of safety” under defined conditions of use. Dose matters.

An NDI is not approval and not a drug application. It is a pre-market safety notification supported by scientific documentation. A proper submission includes botanical identity verification, manufacturing disclosure, ingredient specifications, contaminant limits for heavy metals, microbes, and residual solvents, defined serving sizes and intake limits, toxicological evaluation, exposure modeling, and margin of exposure calculations.

It is a structured scientific process.

We engaged this framework. Through an accredited third-party laboratory operating under FDA guidelines, we conducted a 90-day toxicology study, established a No Observed Adverse Effect Level, calculated margins of exposure, and defined intake parameters. Our submission modeled how the ingredient is absorbed, metabolized, and eliminated to establish exposure boundaries consistent with safety data.

In 2023, a federally conducted Single Ascending Dose human study evaluated tolerability across escalating exposure levels consistent with prior exposure modeling.

Our standardized extract has also undergone the same process as the powder. Additionally, it is also being evaluated in a federally funded clinical study at a renowned US university. These studies do not represent approval, but they contribute to dose-response understanding.

It is important to distinguish between raw botanical material and extract.

Raw kratom is powdered leaf that undergoes harvesting, drying, crushing, and milling. Like any agricultural commodity, it can vary in alkaloid concentration depending on harvest and handling.

A properly manufactured extract, produced under a standardized operating procedure, reduces that variability. It allows defined serving sizes, consistent active marker levels, and reproducible exposure. Extraction removes unwanted constituents such as fibers, fats, and waxes, reduces microbial load, and can reduce contaminants.

Our extract is manufactured in the United States using food-grade green solvents. Our patented process results in a clean, solvent-free ingredient in its finished state. It is mass balanced, meaning the alkaloid profile closely represents what naturally occurs in the plant. Our product does not chemically alter the plant's profile and contains no synthetic spiking or unknown impurities. It improves solubility and predictability, allowing lower amounts to achieve defined exposure.

Extraction is not inherently more dangerous than raw botanical material when supported by proper chemistry, toxicology data, and defined intake limits. When done correctly, extracts represent modernization of botanical safety — consistency, stability, and transparency.

House Bill 587 limits synthetic and semi-synthetic compounds, restricts 7-hydroxymitragynine concentrations, requires alkaloid labeling, and mandates compliance with contaminant standards. Those guardrails improve consumer protection.

Restricting standardized extracts with documented safety data opens the door in the market toward inconsistent raw powders with unverified potency. That increases risk. Regulatory engagement should be encouraged for both powder and natural extract and products using these ingredients.

Engaging the NDI framework demonstrates regulatory maturity. It defines exposure limits, documents manufacturing controls, and participates in existing federal law. Science-based evaluation allows policy decisions to be grounded in exposure modeling rather than uncertainty.

No bioactive compound carries zero risk. The standard is defined exposure and responsible intake.

As a manufacturer, consultant, and Ohio resident, I believe long-term legitimacy requires transparency, standardization, toxicological evaluation, and regulatory participation. The dietary supplement framework already provides a mechanism for documented safety evaluation before sale.

Oversight protects consumers. Defined intake parameters protect consumers. Responsible manufacturing protects consumers.

Thank you for your time and consideration.