

Diversified Botanics Applauds FDA's Formal Action Targeting Synthetic, Concentrated 7-OH

CEO Ryan Niddel supports FDA's scheduling recommendation

SALT LAKE CITY, UT, UNITED STATES, July 29, 2025 /EINPresswire.com/ -- Diversified Botanics today voiced strong support for the U.S. Food and Drug Administration's enforcement actions and regulatory recommendations targeting synthetic, concentrated forms of 7-hydroxymitragynine ([7-OH](#))—a potent opioid analogue found in certain commercial products falsely marketed as [kratom](#).

The FDA's announcement includes a scientific report on synthetic 7-OH, formal warning letters to distributors, and a scheduling recommendation to the Drug Enforcement Administration (DEA) to classify high-concentration 7-OH as a Schedule I controlled substance under the Controlled Substances Act.

The agency emphasized that its action distinguishes synthetic, concentrated 7-OH from the trace levels that occur naturally in the kratom plant.

"This is a public health milestone," said Ryan Niddel, CEO of Diversified Botanics.

□"The FDA is drawing a necessary line between authentic plant-based products and synthetic opioid analogues deceptively labeled and sold to unknowing consumers. We fully support the agency's action and its focus on truth, science, and consumer protection."

The FDA's scientific report and public comments reiterated that natural kratom leaf typically contains $\leq 1\%$ 7-OH, whereas some commercial formulations contain 90–100% synthetic 7-OH—creating significantly higher potency and potential for harm.

Commissioner Dr. Marty Makary stated during the press briefing:

"We are prioritizing regulation of synthetic, concentrated kratom first. We believe there is a clear difference in public health risk between synthetic products and naturally occurring compounds in kratom leaf."

Effective immediately, FDA warning letters have been sent to distributors of synthetic 7-OH products, and the agency confirmed it has received positive responses from some retailers.

In addition, the FDA is issuing a “Dear Doctor” letter to healthcare professionals nationwide, advising them of the safety concerns surrounding these products.

“This is not about banning kratom,” Niddel added. “It’s about eliminating dangerous adulterants and restoring scientific clarity. If we want to preserve access to safe, full-spectrum botanicals, we must reject synthetic shortcuts and prioritize transparency across the supply chain.”

Diversified Botanics does not manufacture or sell synthetic 7-OH products and has long supported the principles outlined in the Kratom Consumer Protection and Safety Act (KCPA), which include 7-OH concentration limits, Certificate of Analysis (COA) requirements, and batch-level traceability.

About Diversified Botanics—Diversified Botanics is a botanical wellness company focused on producing safe, effective, and fully transparent plant-based products. With a commitment to third-party testing, supply chain integrity, and scientific alignment, Diversified Botanics partners with regulatory and academic communities to advance consumer safety. Each product includes a QR-coded COA for full traceability from farm to shelf.

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