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August 21, 2025

Contact: media@hartsupporter.com

LEADING RESEARCHERS REJECT FDA'S POSITION, FIND NO EVIDENCE OF HARM FROM 7-OH IN RESPONSE FROM SHAMAN BOTANICALS TO FDA

[WASHINGTON, DC] Shaman Botanicals has issued a formal response to the FDA's recent warning letter on its 7-Hydroxymitragynine (7-OH) products, **backed by reports from leading researchers at Johns Hopkins, Harvard, UCLA, and other institutions.** The company argues that current scientific evidence supports the safety of 7-OH, directly countering FDA's claims. Experts consulted—including those previously cited by FDA—stress that 7-OH should not be considered a public health crisis and that available data shows no evidence of overdose deaths, respiratory depression, or widespread dependence.

The experts also emphasize that **7-OH is a naturally occurring kratom-derived compound**, not synthetic, and that **preclinical studies commissioned by Shaman found no serious toxicity.** Collectively, the findings point toward a favorable safety profile and call for continued study rather than scheduling. Shaman Botanicals maintains its commitment to scientific transparency and consumer safety, urging FDA to follow the science.

Key Points:

1. Experts previously cited by the FDA now disagree with its recommendation to schedule 7-OH. They argue the agency's position is not supported by the latest scientific evidence.
2. **No deaths or confirmed cases of respiratory depression have been linked to 7-OH.** Researchers claim this is significant given millions of adults are estimated to have tried it.
3. **Researchers say that 7-OH has “no unreasonable risk of overdose deaths”** based on reviews of nationwide databases. Poison control and toxicology centers across the U.S. confirm no evidence of widespread harm.
4. **Scientists confirm that 7-OH is a natural metabolite of kratom**, not a synthetic substance. It is produced both by the plant itself and through metabolism in the human body.

See the full Shaman Botanicals, LLC Response Below:

Shaman Botanicals, LLC Responds to FDA Warning Letter with Scientific Reports by Renowned Experts

Shaman Botanicals, LLC, a leading innovator in botanical wellness, has formally responded to a recent warning letter from the U.S. Food and Drug Administration (FDA) regarding its 7-Hydroxymitragynine (7-OH) products. In support of its mission and to defend its products, attorneys for Shaman Botanicals have assembled an interdisciplinary team of renowned researchers, scientists, and clinicians to prepare reports that directly address the FDA's claims concerning 7-OH.



"The FDA asserts that there is insufficient information about the safety of our 7-OH products. However, the scientists consulted by our legal team have found that the evidence to date supports the safety of our products," stated Stephen "Vince" Sanders, II, founder of Shaman Botanicals.

Scientists Cited by the FDA Express Concerns About the Scheduling of 7-OH

Scientific reviews were provided by **Dr. Kirsten Smith, PhD**, widely regarded as the leading clinical researcher on Kratom in the United States and an Assistant Professor at Johns Hopkins University, and **Dr. Edward Boyer, MD, PhD**, a Harvard-educated medical toxicologist with extensive experience in Kratom research.

The support for further study and regulation of 7-OH products by Drs. Smith and Boyer reflects a growing and dynamic shift in the scientific community's perspective on 7-OH. Work by Drs. Smith and Boyer was cited by the FDA in their recent report recommending the scheduling of 7-OH. Both Drs. Smith and Boyer are currently leading projects to better understand 7-OH use patterns in the United States. But, having looked at the latest data, they do not agree with FDA's position.

Other scientists cited in Shaman's response to the FDA include **Dr. Michael Levine, MD**, a medical toxicologist educated at Chicago Medical School and an associate professor at the University of California-Los Angeles, recognized for his research in botanical toxicology, and **Dr. Jakob Moskovitz, D.Sc.**, a Technion-Israel Institute of Technology-trained biochemist and internationally recognized expert in molecular biology. Drs. Levine and Moskovitz were provided with three preclinical studies commissioned by Shaman and asked to comment on them. Shaman's response also cited **Dr. Glenn Prestwich, PhD**, a Stanford-educated chemist and internationally recognized authority on natural products chemistry and chemical biology, and **Dr. Andrew Monte, MD, PhD**, the Associate Director of the Rocky Mountain Poison & Drug Center in Denver, Colorado, and an expert in nationwide monitoring for adverse events from opioids.

7-OH Should Not be Considered a Public Health Crisis

Dr. Smith strongly disagrees with the FDA's recent recommendation to schedule 7-OH. According to Dr. Smith, the use of 7-OH does not constitute a public health crisis. Furthermore, Dr. Smith asserts that, much like kratom, 7-OH currently offers a net benefit to its users.

According to Dr. Smith, who estimates that at least 4 million adults have tried 7-OH, there are no confirmed human cases of respiratory depression caused by 7-OH. Additionally, reports of physical dependence or substance use disorder related to 7-OH are even rarer than those associated with kratom.

7-OH Is Not Causing Widespread Illness or Injury

Dr. Boyer reviewed nationwide toxicology databases, including poison center data, and found limited evidence of acute overdose risk from 7-hydroxymitragynine. No deaths have been

attributed to 7-hydroxymitragynine, a finding confirmed by America's Poison Center in their August 12, 2025 report.

As Dr. Boyer stated, "A signal arising from overdose death from 7-hydroxymitragynine is absent. Based upon data available at this time, given the degree of population exposure, the lack of findings suggests that 7-hydroxymitragynine carries no unreasonable risk of overdose death."

Dr. Monte arrived at the same conclusion as Dr. Boyer, that there is currently no evidence of a safety signal regarding 7-OH as reported by independent poison control and toxicology centers across the United States.

Dr. Boyer also disagreed with the FDA's report regarding the putative safety or danger of 7-OH. According to Dr. Boyer, the FDA assessment relies on animal studies receiving intravenous 7-hydroxymitragynine (a route of administration never used in humans) and overlooks existing data indicating low bioavailability, rapid clearance, and poor brain penetration characteristic of oral 7-hydroxymitragynine.

7-OH is a Natural Product; Not Synthetic

Opponents of 7-OH often mistakenly label these kratom-derived products as "synthetic." According to Dr. Prestwich, "7-OH is not manufactured synthetically." Instead, 7-OH is a naturally occurring selective oxidation product of mitragynine, already present among the indole alkaloids in kratom plant extract. These products contain 7-OH that is chemically identical to the natural metabolite of mitragynine produced by the kratom plant and through metabolism in the human body. Thus, 7-OH is a natural product.

Pre-Clinical Data Conducted by Shaman Botanicals Supports the Favorable Safety Profile of 7-OH

Drs. Levine and Moskovitz each reviewed three preclinical studies commissioned by Shaman: (1) "Acute Toxicity Assessment of 7-Hydroxymitragynine in Rodents," (2) "Pilot Safety Study of Escalating Doses of 7-Hydroxymitragynine and Mitragynine Pseudoindoxyl Administered Daily for 7-day Intervals to Mature Dogs," and (3) "An In-Vitro Pre-Clinical Safety Comparison of Mitragynine and its Oxidative Metabolites: 7-Hydroxymitragynine and Mitragynine Pseudoindoxyl." In the two animal studies, no serious clinical toxicity or adverse events were observed.

Dr. Levine stated these studies support initial safety and warrant further evaluation. Dr. Moskovitz concluded, "Based on all the obtained data (i.e., in vitro studies, mice and dogs' models), it seems that the therapeutic potency and safety profile of 7HMG are either the same or better compared to mitragynine."

Current Science Supports a Reasonable Basis of Safety and Recommends Continued Study, Not Scheduling

Full copies of each expert report have been provided to the FDA. “The FDA pledged to follow the science. The aforementioned experts, some of the top scientists in the world, maintain the science supports a reasonable basis of safety in our 7-OH products” Sanders said.

Commitment to Transparency and Consumer Safety

Shaman Botanicals remains deeply committed to transparency, scientific rigor, and consumer welfare. The company welcomes continued dialogue.

