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FDA pilot study on kratom leaf concludes botanical 'is well tolerated'

The preliminary results of the study may belie some of the concerns expressed by the U.S. Food and Drug Administration.



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FDA set out to assess the abuse potential around kratom. For years, the agency has warned consumers about the leaf, citing the presence of alkaloids that bind with certain opioid receptors. But the preliminary results of the pilot study may belie some of the concerns expressed by FDA, suggesting kratom — at least in leaf form — is well tolerated.

The preliminary results of the study were presented in January at the University of Florida's International Kratom Symposium. Chad Reissig, supervisory pharmacologist with the Controlled Substance Staff at FDA's Center for Drug Evaluation and Research, delivered the findings. Reissig served as one of the pilot study's researchers.

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Researchers, following FDA's guidance for the initial investigation, carried out a single ascending dose (SAD) trial. Such an approach “tries to establish a dosing range where we can say at this dose it appears to be safe and not cause any adverse events,” said Christopher McCurdy, Ph.D., one of the lead scientists for the study. McCurdy, professor of medicinal chemistry at the University of Florida, has evaluated kratom for nearly 20 years.

The pilot study comprised 40 people, some of whom received placebos. Each participant had to be healthy with no history of substance abuse and accustomed to taking a range of recreational drugs and opioids. FDA leaders insisted on that framework for ethical reasons.

They “did not want to, in any way, shape or form, push somebody into a situation where, all of a sudden, they were rushing out to get kratom or some other drug ... because they had this euphoric experience that they've never had before,” McCurdy explained in a phone interview with SupplySide Supplement Journal (formerly known as Natural Products Insider). “They didn't want it to be like a gateway initiator, if you will.”

While such a risk with kratom “is probably very low,” McCurdy added, the pilot study needed to err on the side of safety. That's a key reason why the trial relied on the SAD structure.



temperature. They also watched for any adverse events.

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Nothing serious happened.

“Vomiting was the most common [adverse event] and showed an increased trend in the higher dose range (i.e., 8, 10 and 12 g) compared to the lower doses,” McCurdy and his colleagues wrote in the study’s discussion section of a one-page summary from FDA.

One of the biggest reasons for that reaction at the higher doses probably correlates to the number of capsules participants had to ingest. The 12-gram group had to take 24 capsules containing 500 milligrams of kratom leaf powder within five minutes.

That amount “is not nearly equivalent to Joey Chestnut on the Hot Dog Eating Contest, but it’s certainly a tremendous amount of bulk that you’re putting into the stomach,” McCurdy said. “So it’s no surprise that we had nausea, and we had some irritability in some of those individuals.”

The only other “small effect” researchers saw was some minor pupil dilation. That’s “typical” considering that kratom binds to opioid receptors, McCurdy explained.

All told, the study — which has not yet undergone peer review — noted: “The data suggest that at the doses tested, using the specific botanical kratom sourced for the study, and under carefully controlled clinical conditions ... kratom was well tolerated.”

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Release of the study “provides the opportunity for the FDA to reset its long-standing war on kratom,” said Mac Haddow, senior fellow on public policy with the American Kratom Association (AKA), “and take responsible steps to regulate kratom to protect consumers from deliberately adulterated products; untested kratom products that may have microbial contamination; remove products making illegal therapeutic claims; removing dangerously concentrated products that do not use food grade solvents to limit concentrations; and requiring good manufacturing practices for all kratom products.”



associated with kratom, including kratom extracts and other substances isolated or synthesized from kratom, including 7-hydroxymitragynine (7-HMG) — and more research is needed.

“It is unclear how the single-sourced, botanical kratom used in our study compares to the wide array of kratom-related products available in the marketplace,” according to the one-page summary of the study. “Though data are limited, the mitragynine and 7-HMG content of the kratom used in our study is consistent with that reported in the literature. However, more than 50 alkaloids exist in the kratom plant that may have pharmacological effects. Importantly, there is a growing trend of newly created kratom ‘extracts’ that have enriched and increased levels of kratom alkaloids, including increased levels of mitragynine and 7-HMG.”

Scientists used kratom capsules from Super Organics LLC (doing business as Super Speciosa). The company subjects its products to third-party testing and provides a QR code on the label, linking to certificates of analysis to confirm the authenticity of the herbal ingredients, that the product contains no adulterants or contaminants and that the label accurately matches the alkaloid content.

“The industry is [under a microscope](#), and we really want to go above and beyond and show people that we’re doing things the right way,” said Ken Loricchio, a co-founder of Super Speciosa, who hopes the pilot study buoys perceptions about high-standards kratom.

“We want to be regulated,” he said. “We want to be treated like we are a legitimate industry. We know that the industry has real problems — there’s no shying away from that — but these are fixable problems.”

‘We need to do a lot more research’

The pilot study, though, represents just the first official step toward determining kratom’s abuse potential. The limiting nature of the SAD approach means that regulators must decide whether to next conduct a multiple ascending dose version, McCurdy shared.

“Who knows what they’ll do? It’s a mystery,” the kratom researcher commented.

An FDA spokesperson did not indicate when the agency might take on more kratom research, or in what form.

“We recognize that further studies are needed to advance [our understanding of kratom](#),” the FDA spokesperson told SupplySide Supplement Journal via email.



a basic science community and as a medical community, how to address those patients properly and treat them properly, because we really don't understand the entirety of the effects of what kratom is doing."

But, he added, the results of this FDA pilot effort pave the way for scientists to keep exploring kratom.

"The encouraging fact of this study is that we were able to successfully complete all the dosing cohorts without any significant adverse events," McCurdy said. "That leaves the door open for more research, particularly at those doses."

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