

Consumer Advisory
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CONSUMER WARNING ON ENHANCED 7-HYDROXYMITRAGYNINE ("7-OH") PRODUCTS

All consumers are warned that products that isolate, purify, or concentrate the 7-OH metabolite above levels that naturally occur in the kratom plant are not real kratom products and they unambiguously violate specific provisions of the Federal Food, Drug, and Cosmetic Act.

GAINESVILLE, VA — The AKA warns consumers that any product with a 7-OH content that exceeds more than 2% of the total alkaloid fraction of the overall constituent content of the kratom plant poses a significant safety risk to consumers.

Many new 7-OH products entering the market claim to be "Advanced Kratom Alkaloids" or "7-Hydroxymitragynine+MIT." These products mislead kratom consumers into believing that they have the same safety profile of kratom that has been used safely for decades in the United States, and for centuries in Southeast Asia.

Consumers are warned that these products have a greater risk of abuse liability and put consumers at significant risk for adverse events from consuming these products.

The AKA asks every consumer to consider the following facts about enhanced 7-OH products:

- A 7-OH synthetically enhanced product IS **NOT A KRATOM PRODUCT AND CONSUMERS SHOULD NOT BE DECEIVED INTO THINKING THEY ARE.**
- It is standing FDA policy that a synthetic copy of a botanical or constituent of a botanical <u>DO</u> <u>NOT</u> meet the FDCA's definition of a dietary ingredient.¹
- The consensus of leading scientists is that 7-OH enhanced products have a greater abuse liability and a higher risk for adverse events. There is currently no valid scientific literature that supports any claim that 7-OH is safe at artificially increased levels.
- 7-OH enhanced products will empower the FDA to seek another ban on kratom at the federal and state levels.

Consumers should not purchase any enhanced 7-OH product because they pose a real safety threat to anyone who consumes these products.

¹ U.S. Food and Drug Administration. (August 2016). *Dietary Supplements: New Dietary Ingredients Notifications and Related Issues: Guidance For Industry,* Draft Guidance. Washington DC.