



KRATOM FACT SHEET

THE FDA’S ROLE IN DEMONIZING A SAFE BOTANICAL

Dispelling Myths and Understanding Facts

Nearly 5 million Americans safely use kratom as a part of their health and well-being regimen and have done so for decades. Kratom is regulated by the U.S. Food and Drug Administration (FDA) as a dietary ingredient/supplement, and people who use kratom do so for the same reasons as people who use dietary ingredients, supplements, and who drink coffee, tea, or other caffeinated beverages. Surveys show that kratom consumers are educated, middle-income, employed, and have health insurance – they are largely the soccer moms and dads of America.

The FDA has repeatedly attempted to force kratom into Schedule I of the Controlled Substances Act by misstating the science, ignoring kratom’s long history of safe use, and falsely claiming kratom has the same effects as classic opioids. The FDA’s distorted record on kratom is clearly a part of the FDA’s long-standing bias against dietary supplements that are safely used by millions of Americans rather than chemical drug formulations that are subject to new drug applications that have their own potential and frequently serious adverse health impacts.

Dispelling the FDA Myths	Understanding the Facts
<p>There are 44 kratom associated deaths between 2009 and 2016.</p> <p>Kratom’s primary alkaloids, mitragynine (MG) and 7-hydroxymitragynine (7-HMG) are dangerous opioids and have the same effects of opioids like heroin.</p> <p>Kratom is highly addictive and is abused as a drug.</p> <p>The kratom industry has no production standards or consumer safety protocols.</p>	<p>There has not been a single documented fatality that can be linked to use of the natural kratom plant. The FDA claimed deaths “associated with kratom use” are actually deaths caused by polydrug use, underlying medical conditions, or the use of adulterated kratom products laced with toxic levels of dangerous substances, including opioids. National Institutes on Drug Abuse’s (NIDA) newly-updated conclusions agree that kratom use does not cause overdose deaths.</p> <p>MG and 7-HMG, like many other substances like Chamomile, St. John’s Wort, etc., do bind to the mu-opioid receptors in the brain. Kratom’s alkaloids are actually only partial agonists, with lower dependence and abuse potential. Most importantly, scientific evidence demonstrates that kratom does not cause respiratory depression like classic opioids, a common cause of fatal overdoses.</p> <p>Like coffee, tea, and other caffeinated drinks, consumers can develop a dependency on kratom, which is vastly different from an addiction. Two new scientific studies completely debunk the FDA theory. The Hemby study in June 2018 concluded “MG does not have abuse potential and reduces morphine intake,” and the Yue study in July 2018 reported “limited abuse liability and potential for mitragynine treatment to specifically reduce opioid abuse.”</p> <p>Kratom consumer advocacy groups and kratom manufacturer trade associations are committed to providing consumers with safe, high-quality kratom products. The kratom community supports adherence to FDA product testing protocols that meet or exceed Good Manufacturing Practice (GMP) guidelines set by the FDA for dietary ingredients/supplements and support appropriate age restrictions and labeling guidelines outlining responsible use. The kratom community calls upon the FDA to use its existing regulatory authority to remove adulterated kratom products from the market and prosecute individuals or companies who produce or distribute dangerous adulterated kratom products.</p>

The kratom community believes public policy related to kratom should follow the science. To learn more about the science that supports the fact that kratom is a safe natural botanical, and why the FDA claims being made about kratom are just wrong, visit the following page to download and review the compelling truth about kratom use: <http://americankratomassociation.org/index.php/mediak/congressional-briefings>