



October 24, 2018

Elyse Greenwald
SAMHSA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building, Room 10102
Washington, DC 20503

Dear Ms. Greenwald:

We represent manufacturers, vendors, and consumers of kratom. We are writing to object to the inclusion of questions about kratom use in the National Survey on Drug Use and Health (NSDUH). Questions about kratom are outside the scope of the NSDUH and therefore are inappropriate.

As noted in the Federal Register notice published on October 5, 2018, data from the NSDUH “are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs.” Kratom does not fall within any of those categories and therefore questions about kratom should not be included in the NSDUH.

Kratom is regulated by the US Food and Drug Administration (FDA) as a dietary ingredient/supplement. It is derived from a plant in the coffee species and has been used for decades in the U.S.. Millions of Americans eat or drink kratom every day to improve their overall well-being. As such, it clearly is not a tobacco product, is not alcohol, and is not an illicit substance.

In addition, kratom has never met the definition of a drug under federal law. As you know, a “drug” is defined by FDA as a substance “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” or a substance “intended to affect the structure or any function of the body.”¹ Kratom is not intended for any of those purposes. Obviously, if kratom is not a drug it cannot be a “prescription drug.”

We also object to the statements in the Federal Register notice characterizing kratom as an “easily accessible, unregulated, opioid-like drug.” Moreover, the Federal Register notice states kratom’s compounds “interact with opioid receptors in the brain.” It further states that “[s]ome users of kratom products reported becoming addicted to the drug.”

First, and as noted earlier, kratom is neither unregulated nor a drug. It is regulated currently by FDA as a dietary ingredient/supplement since it does not meet the legal definition of a drug.

¹ Drugs@FDA Glossary, <https://www.fda.gov/drugs/informationondrugs/ucm079436.htm#D>, viewed on 10/17/18.

In addition, while the alkaloids in kratom attach to the mu-opioid receptors, the Federal Register notice inappropriately suggests kratom is a dangerous opioid—emphasized by the statement about addiction. As such, these statements are misleading.

Numerous published scientific analyses have found that kratom is not a dangerous opioid. Unlike addictive opioids, kratom does not cause respiratory distress or depression and has a low potential for abuse. In fact, a recent study funded in part by the National Institute on Drug Abuse (NIDA) confirmed that the main kratom alkaloid does not have abuse or addiction potential.² Moreover, a study conducted under NIDA's Intramural Research Program affirmed that "results suggest a limited abuse liability of mitragynine and potential for mitragynine treatment to specifically reduce opioid abuse."³ In addition, many people who consume kratom report that it helps them avoid use of dangerous and addictive opioids.

This and other newly published research needs to be fully evaluated before any specific survey questions are developed. As currently proposed, the inclusion of the kratom as proposed in the Federal Register notice suggests a clear bias about kratom, which in turn would generate heavily biased data. This would add to the current controversy, and not address the outstanding questions that must be resolved before the SAMHSA's survey could properly be framed to provide reliable results.

As noted, we believe it would be inappropriate to include questions about kratom in the NSDUH. Given SAMHSA's interest in including kratom questions in the NSDUH which is outside the survey's scope, and the mischaracterization of kratom throughout the Federal Register notice, we are concerned that SAMHSA has a pre-conceived opinion of kratom which will influence the phrasing of the questions.

Therefore, if SAMHSA insists on using NSDUH to gain information about kratom use, we strongly urge the administration to work with the many scientists and addiction specialists who have studied kratom when developing survey questions. Our organizations would be happy to be a resource for the agency on this topic as well.

Thank you for your consideration of our comments.

² Abuse Liability and therapeutic potential of the *Mitragyna speciosa* (kratom) alkaloids mitragynine and 7-hydroxymitragynine, *Addiction Biology*; Hemby, McIntosh, Leon, Cutler & McCurdy, published on June 27, 2018.

³ Yue K, Kopajtic, Katz, Abuse liability of mitragynine assessed with a self-administration procedure in rats, *Psychopharmacology*, 2018, <https://www.ncbi.nlm.nih.gov/pubmed/30039246>