



FDA Fails To Provide Credible Data And Science To Justify Scheduling Kratom As Schedule I Substance

New Report Released by the American Kratom Association

FOR IMMEDIATE RELEASE

WASHINGTON, DC - DEC. 20, 2018 – The U.S. Food and Drug Administration’s efforts to have kratom listed as a Schedule I substance under the Controlled Substances Act (CSA) is filled with errors and omissions, according to a [new report from the American Kratom Association \(AKA\)](#). The AKA report maintains that FDA fails to meet the burden of proof necessary to propose such a radical change in Kratom’s regulatory status.

“To meet the standard, which would put kratom on par with heroin, LSD, Quaaludes, and peyote, the FDA must submit an eight-factor analysis that conclusively demonstrates with scientific evidence that kratom is dangerously addictive and presents a risk to the safety of the public,” explains Charles M. “Mac” Haddow, Senior Fellow of Public Policy at the American Kratom Association. “They have clearly failed to meet that prerequisite.”

Haddow says past and ongoing academic research is extremely important to resolve the claims being made by the FDA.

“First, as demonstrated through numerous studies on animals, kratom has very low toxicity. In such studies, even extremely high doses—doses that, when adjusted for humans, would be difficult to consume—do not cause death or significant toxic effects,” Haddow says. “Follow the science. Kratom itself is safe. The science is clear.”

The [27-page report](#) points to an analysis published in the [American Chemical Society Medicinal Chemistry Letters](#) in 2017 that found that withdrawal from kratom is milder than withdrawal from opiates and stated that the “most significant advantage of kratom is that it has not caused any overdose deaths.” That analysis is a part of a nearly-decade-long effort by the scientific community

and kratom advocacy groups that have provided “substantial credible evidence that contradicted the FDA claims” that kratom is harmful.

The report notes not only the mild addiction profile of kratom, but its safety profile demonstrating centuries of regular use without serious incident, particularly in Southeast Asia. After a similar battle with the FDA two years ago—in which similar facts were presented—the Drug Enforcement Agency (DEA) withdrew its Notice of Intent to place kratom on the Schedule I register.

Despite peer-reviewed science, the FDA has claimed that kratom has been responsible for 44 deaths. But the report found that the majority of the death data relied upon by the FDA implicates the use of multiple drugs, underlying health conditions, or the use of adulterated kratom products. “It’s not kratom itself that is the problem,” Haddow says. “Again, the science is clear, and the FDA should acknowledge that.”

Alkaloid levels in the natural plant kratom are not dangerously addictive, and do not have the same pharmacologic effects as classic opioids that attack the respiratory system of users. According to the report, “There is no credible scientific literature that proves kratom has any effect on the respiratory system of any user that is typically associated with deaths from the use of classic opioids.”

Kratom comes from Southeast Asia where it has been used as a traditional medicine for hundreds of years. It is in the same tropical evergreen tree in the coffee family and has similar mild addiction characteristics to caffeine.

In February, nine leading scientists sent a letter to the White House and DEA warning about the consequences of scheduling kratom as proposed by the FDA. They stated in their letter that placing kratom on Schedule I “will potentially increase the number of deaths of Americans because many have been using kratom will revert to dangerous and addictive drugs.”

If kratom is listed as a Schedule I substance it will make it illegal for any of the nearly 5 million consumers who currently safely use kratom to purchase or use kratom in the United States.

ABOUT AKA

The American Kratom Association (AKA), a consumer-based non-profit organization, advocates to protect the freedom of consumers to safely consume natural kratom as a part of their personal health and well-being regimen. AKA represents the nearly 5 million Americans who consume kratom safely each year. www.americankratom.org