



STATEMENT ON DECISION BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES RESCINDING THE SCHEDULING RECOMMENDATION FOR KRATOM

*Mac Haddow, Senior Fellow on Public Policy, American Kratom Association
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The American Kratom Association (AKA) represents the 11 – 16 million American consumers of kratom and expresses its gratitude to Congressman Mark Pocan (WI) for his tireless efforts to require that science dictate the policy on access to safe kratom products in the United States.

The AKA applauds Congressman Pocan and Congressman Morgan Griffith (VA) for their diligent oversight of HHS that led to the release of a rescission notice submitted by the U.S. Department of Health and Human Services (HHS) to the Drug Enforcement Administration (DEA) withdrawing the prior recommendation to schedule kratom's alkaloids, mitragynine and 7-hydroxymitragynine, that had been submitted on October 17, 2017. This document will have a significant impact on implementing the right policy to protect American consumers from adulterated and contaminated kratom products.

The decision by the FDA to not disclose the rescission of their recommendation for scheduling of kratom that took place more than 2 ½ years ago has significantly misled policy makers, the media, and kratom consumers in the belief a scheduling decision was imminent. That proposed scheduling was withdrawn, and the HHS letter outlines specifically how the FDA failed to meet its burden required by the CSA to justify a scheduling of kratom's alkaloids.

The FDA's messaging about kratom tied to its recommended classification as a Schedule I substance has had enormous negative public policy outcomes. Public health policy makers, state legislators, county commissioners, city councilmen, law enforcement groups, medical examiners and coroners, researchers, and substance addiction specialists have all been misled into supporting an FDA narrative on kratom tied directly to the claims that kratom should be banned and that scheduling was imminent.

Six states were duped by this messaging to pass bans on kratom sales, and a number of local county and city governments also based their bans on the FDA's claims. There are kratom ban proposals currently pending across the country where kratom critics point to the FDA's scheduling recommendation and false claims that the DEA scheduling of kratom is "imminent." Media reports over the past 2 ½ years regularly cited the FDA's claims about kratom qualifying as a Schedule I substance and repeat the narrative that the DEA is about to issue a kratom ban.

Through all of this the FDA has remained silent and has failed to disclose that HHS reviewed their scheduling recommendation and took the unprecedented action to rescind the recommendation because the FDA had failed to meet its burden under the CSA.

The HHS recission letter correctly concludes that kratom's alkaloids should not be scheduled until "scientific research can sufficiently support such an action." The letter identifies the specific criteria required for scheduling under the Controlled Substances Act (CSA) that has not been met for kratom and outlines numerous scientific analysis and public input required before any scheduling of kratom should be undertaken in the future.

The HHS recission letter also outlines the consequences of the failure to disclose the recission of the scheduling recommendation citing the "significant risk of immediate adverse public health consequences for potentially millions of consumers" that are the same as kratom actually being scheduled:

- Discourage kratom consumption for those suffering from intractable pain;
- Kratom users switching to highly lethal opioids, including potent and deadly prescription opioids, heroin and/or fentanyl, risking thousands of deaths from overdoses and infectious diseases associated with IV drug use;
- Inhibition of patients discussing kratom use with their primary care physicians leading to more harm;
- The stifling effect of classification in Schedule I on critical research need on the complex and potentially uses chemistry of components of kratom.

It is our hope that by making this decision public, restraints on new needed research will be removed, and existing research initiatives can proceed without the cloud of a potential imminent scheduling decision.

A perverse outcome of the FDA's failure to make a timely and appropriate disclosure of the recission of its scheduling recommendation for kratom is obvious: Failing to disclose the recission allowed the FDA to achieve an almost "*de-facto*" ban on kratom.

The faith the American people have in the FDA to fulfill their mission to protect the safety of the American people should not be compromised because some in the Agency have an expansionist regulatory agenda that exceeds the authority granted to them by Congress.

Today, American consumers remain at significant risk for what is a largely unregulated marketplace for kratom products, and the AKA believes that has to change immediately. AKA hopes to partner with the U.S. Food and Drug Administration (FDA) to establish an appropriate regulatory framework to protect consumers:

- Aggressively remove potentially deadly adulterated kratom products marketed by unscrupulous vendors who spike kratom products with dangerous substances like heroin, morphine, and fentanyl purely for private economic gain.
- Issue recalls on any kratom products that are sold by vendors making impermissible and illegal therapeutic claims that mislead consumers to purchase one kratom product over another for private economic gain. Those vendors can submit a New Drug Application (NDA) if they want legal authority to make such claims.

- Establish regulations appropriate for kratom that assure all kratom products are manufactured under FDA good manufacturing practice (GMP) standards for foods.
- Secure the supply chain to assure that kratom raw materials imported into the United States meet the FDA standards for botanical products available to consumers, with appropriate standards for harvesting, processing, shipping, and testing to assure compliance with FDA standards.
- Allow for any kratom manufacturer who formulates a kratom product as a dietary supplement and seeks to make appropriate labeling claims for marketing of that product to have a fair and unbiased review of a New Dietary Ingredient (NDI) Notification.

The threat to American consumers is in contaminated and adulterated kratom products, and poorly formulated kratom products that are not manufactured according to GMP standards. Bad-actors have been free to undermine legitimate kratom vendors in the marketplace with cheap products precisely because they avoid the costs of equipment, processing standards, testing, and employee training that should be regulated by the FDA. The AKA looks forward to partnering with the FDA to put standards in place to allow consumers to make informed decisions in purchasing safe kratom products to maintain their health and well-being.

Mac Haddow
Senior Fellow on Public Policy
The American Kratom Association
mhaddow@americankratom.org
(571) 294-5978