AMERICAN KRATOM ASSOCIATION

September 4, 2024

The Honorable Robert Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sent via email on September 4, 2024

Dear Dr. Califf:

The American Kratom Association (AKA), representing the more than 20 million Americans who safely use kratom products, urges your attention to the ongoing regulatory discussions surrounding kratom (*Mitragyna speciosa*), a natural plant product that has been used by millions of Americans for various health and well-being purposes. Specifically, the AKA requests you direct your Stakeholder Engagement staff to convene a public stakeholder meeting on kratom to better inform the FDA policy making process in regulating kratom.

Kratom products have been the subject of significant public interest and debate, particularly concerning its safety, benefits, potential for misuse, and, perhaps most importantly, proper regulatory status of such products under the Federal Food, Drug, and Cosmetic Act (the Act). While AKA understands the FDA's commitment to protecting public health, we believe that an open and transparent dialogue with stakeholders, including consumers, healthcare professionals, legal scholars, researchers, and advocacy groups is essential in ensuring that any needed future regulatory decisions regarding kratom products are well-informed and consider all perspectives.

It is important to note that the FDA has made two separate recommendations to classify kratom as a Schedule I substance, both of which have been rejected - first on October 13, 2016, by the DEA[1] and a second time by the HHS Assistant Secretary of Health on August 16, 2018.[2]

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[1] See: https://www.federalregister.gov/documents/2016/10/13/2016-24659/withdrawal-of-notice-of-intent-to-temporarily-place-mitragynine-and-7-hydroxymitragynine-into (last accessed on August 28, 2024).

[2] See: https://www.dropbox.com/s/kag17q07edco5ij/HHS%20Rescission%20Letter%20Dr.%20Giroir%20Aug%2016%202018.pdf?dl=0 (last accessed on August 28, 2024).

These actions reflect a broader recognition among experts that the evidence supporting such a classification does not meet the statutory requirements of the Controlled Substances Act ("CSA").

Furthermore, in December 2021, the Expert Committee on Drug Dependence (ECDD) at the World Health Organization and the U.S. Commission of Narcotic Drugs, comprised of 12 international experts on substance safety and addiction, unanimously concluded that there was insufficient evidence to recommend a critical international scheduling review of kratom. The ECDD's decision highlights the lack of sufficient evidence to justify the strict scheduling of kratom and suggests that a more measured approach is appropriate.

"People report using kratom to self-medicate a variety of disorders and conditions, including pain, opioid withdrawal, opioid use disorder, anxiety and depression," ECDD said in its report. "Kratom is being used as a part of traditional medicine in some countries. The Committee considered information regarding the traditional use and investigation into possible medical applications of kratom," it continued. "The Committee concluded that there is insufficient evidence to recommend a critical review of kratom."[3]

These scientifically based determinations to not schedule kratom, made by both domestic and international bodies, underscore the need for the FDA to reconsider its position on kratom, which should include consideration of these expert evaluations along with all relevant and current scientific and history of use information.

The FDA Position that Kratom is Dangerous:

While the FDA has previously maintained the position that kratom products pose a danger to the public, the agency specifically refused to participate in a Hearing ordered by a Federal Judge scheduled on February 8, 2024, in the Southern District of California. A subpoena was issued that would have required FDA to provide witnesses and documents which would support their claims that kratom is a dangerous substance. FDA and the Department of Justice fought this subpoena and in an email from the Assistant U.S. Attorney, the following explanation was provided to the Court regarding why the FDA was refusing to participate in the Hearing:

> "They [FDA] have refused to provide us with witnesses or documents to support our position . . . The reason they gave was that **they have not yet made a determination regarding whether kratom is dangerous**."[4] (***emphasis added***)

[3] See: https://www.who.int/europe/publications/i/item/9789240042834 (last accessed on August 28, 2024).

[4] Case 3:23-cr-00179-TWR Filed 12/06/23 Page ID.1032 Exhibit 6; United States of America, Plaintiff, v. Nine2Five, LLC (1) Sebastian Guthery (2), Defendants

An apparent reason for FDA's divergence from its publicly stated position is likely a result of FDA's recently completed a Single Ascending Dose ("SAD") study regarding whether kratom can be safely consumed by humans; an abstract of the results of that study were reported at the 3rd International Kratom Symposium in Orlando, Florida on February 16, 2024. This study concluded that "kratom appears to be well tolerated in humans at all dose levels." The highest single amount of kratom consumed during one occasion as part of this study was a staggering 12 grams.

In the SAD study, the FDA found that only two human subjects, out of the 40 participants, experienced nausea only after the consumption of 12 grams of kratom (24 capsules) within 5 minutes. A similar reaction was experienced by a comparable number of subjects among the placebo group, showing this reaction was more likely due to the high volume of material consumed within the required 5-minute period, and not specifically due to the consumption of kratom. Nausea, by itself, is not typically identified as a serious adverse event, and none of the subjects reached the study's "stopping criteria" that would have resulted in termination of the study.

This key finding of the safety of kratom cleared the solicitation by the FDA for proposals to conduct a Human Abuse Potential ("HAP") study to determine whether kratom use results in dependency or addiction, and the severity if indicated. The notice for solicitation for the HAP study was issued on January 16, 2024.[5] This study is expected to be completed in approximately 3 years.

This dose-finding study conducted by the FDA on kratom appears to contradict the agency's public stance on kratom being inherently dangerous. This raises significant questions about the justification for the FDA's strong opposition to kratom products and suggests that a more nuanced and exact approach to the regulation of kratom products is warranted. A fair assessment of the results of this study should prompt a reevaluation of the FDA's current position and encourage a more balanced and evidence-based discussion about the potential benefits and risks of kratom products.

Additionally, new scientific research funded by the National Institute on Drug Abuse (NIDA) has concluded that kratom may serve as a valuable harm reduction tool in the ongoing opioid crisis. On May 17, 2022, Dr. Nora Volkow, Director of NIDA, testified regarding the drug overdose crisis at a hearing of the U.S. Senate Subcommittee on Labor, Health and Human Services. When asked about overdose prevention strategies, Dr. Volkow stated: "There's also interest in the community to *test other products that may serve as harm reduction*. For example, *the use of kratom, which is sold as tea and that contains a drug molecule that has effects that are*

[5] See: https://grants.gov/search-results-detail/351644 (last accessed August 28, 2024).

similar to a dose of buprenorphine but could be utilized also for decreasing withdrawal or depression."[6] (*Emphasis added*.)

NIDA Director Volkow continued her testimony before the US House of Representatives Appropriations Committee and stated the following:

> "Kratom, most notably mitragynine, has many interesting properties that could be of value potentially as a medication for pain. Also, interestingly, they could hold value as a treatment for addiction […] it is important to actually do research on this substance."[7]

This research and research like it indicate that kratom could potentially help individuals struggling with opioid dependence by providing a safer alternative that mitigates withdrawal symptoms and reduces the risk of overdose. Given the severity of the opioid crisis, and the urgent need for effective harm reduction strategies, these findings should not be overlooked. It is critical that the FDA considers this emerging evidence and the potential public health benefits of kratom products in its regulatory approach.

The FDA Import Alert on Kratom Raw Materials:

The AKA is deeply concerned that the current import alert on kratom, which effectively prevents entry of kratom raw materials into the United States, functions as an unauthorized and impermissible ban on the substance. This action has far-reaching consequences for the many Americans who rely on kratom for their well-being. By blocking kratom imports without a formal Schedule I determination under the CSA, adequate consideration of the available scientific evidence, and the true regulatory status of kratom products under the Act, FDA has bypassed the necessary regulatory processes. This import alert undermines the principles of due process, fairness and transparency that are fundamental to our regulatory system and required under the Act.

The FDA Webpage on "FDA and Kratom":

The AKA is concerned that the FDA's webpage, "FDA and Kratom," makes unfounded conclusions that kratom is inherently dangerous.[8] In apparent reliance on outdated information, the webpage presents kratom as posing significant health risks without adequately

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[6] Hearing on the FY 2023 Budget Request for the National Institute of Health Before the S. Appropriations Subcomm. On Labor, HHS, Education, and Related Agencies,117th Cong. (2022) (statement of Dr. Nora Volkow at 38:30).

[7] https://appropriations.house.gov/events/hearings/fy-2022-budget-request-for-the-national-institutes-of-health

[8] See: https://www.fda.gov/news-events/public-health-focus/fda-and-kratom (last accessed August 28, 2024).

acknowledging the current body of scientific evidence that suggests otherwise. This one-sided portrayal fails to consider the nuanced nature of kratom's effects, as well as the personal testimonies of countless individuals who have found kratom to be beneficial. This approach does not align with the FDA's commitment to science-based regulation and public health, and it further underscores the need for a comprehensive and balanced review of all currently available evidence.

The AKA is also troubled by the fact that personal injury trial attorneys are leveraging the FDA's outdated and biased position on kratom to bolster their product liability claims. By citing to FDA's statements and actions against kratom, these attorneys are able to strengthen their arguments in court, often leading to settlements or judgments that do not reflect the actual risk profile associated with kratom. This not only creates a chilling effect on the availability of kratom for those who rely on it and limits legitimate scientific and social research but also perpetuates misinformation and fear among the public. It is imperative that the FDA ensures its public statements concerning kratom are based on balanced and objective evidence and are of a scope and tone that avoids inadvertently influencing legal outcomes in a manner that may harm to consumers.

Since the conclusion of the above-mentioned reviews by the DEA, HHS, and the ECDD, the FDA itself has received additional substantial scientific evidence pertaining to the safety and addiction profile of kratom that not only support the independent reviews, but also directly and substantively contradict the statements made by FDA on its "FDA and Kratom" webpage. These incorrect, unsubstantiated, and biased claims about kratom constitute the very kind of disinformation you, Dr. Califf, have personally criticized and point to as the basis for your current "FDA Rumors" campaign to ostensibly protect the public health.

The FDA continues to rely on the same outdated and stale evidence and data it used to support its scheduling recommendations for kratom – material that former Assistant Secretary of Health Brett Giroir described as "embarrassingly poor evidence and data"[9]. Dr. Giroir, a respected public health official, criticized the evidence as insufficient and not meeting the rigorous standards necessary for justifying such strong regulatory actions. The continued reliance on this flawed data by the FDA undermines the credibility of the agency's stance on kratom products, and calls into question the validity of the conclusions FDA draws from it. It is crucial that the FDA reevaluate its position relative to kratom products by considering more robust and comprehensive scientific research thus ensuring that any regulatory decisions are grounded in sound evidence.

[9] See: https://x.com/DrGiroir/status/1395874443726102533 (last accessed August 28, 2024).

The FDA Abuse of the New Dietary Ingredient (NDI) Notification Process:

The AKA is very concerned that the FDA is abusing the NDI notification process to effectively restrict kratom products from the marketplace. By consistently objecting to NDI submissions for kratom products based on broad and arguably unfounded safety concerns, the FDA is preventing the lawful introduction of kratom into the dietary supplement market. This approach not only stifles innovation and consumer access, but also disregards FDA's own regulatory pathway that allows for safe and responsible use of natural products. The misuse by FDA of the NDI process to impose de facto restrictions on kratom products is contrary to the intent of the Dietary Supplement Health and Education Act (DSHEA) and undermines consumer choice and access to potentially beneficial products.

The FDA Consumer Alert on OPMS Black Liquid:

The AKA would also like to address the FDA's Consumer Alert regarding the OPMS Black liquid kratom product.[10] The alert, which warns consumers of potential health risks associated with this specific product, seems to be based on limited and anecdotal evidence rather than comprehensive scientific data. The FDA's characterization of OPMS Black as particularly dangerous contributes to a narrative of fear and misinformation surrounding kratom products, without offering sufficient evidence to substantiate these claims. It is essential that the FDA ensures that any consumer alerts are grounded in solid, peer-reviewed research to avoid unjustly damaging the reputation of specific products or the kratom industry as a whole. A more balanced and evidence-based approach is necessary to maintain public trust and provide consumers with accurate information.

It is also concerning that the FDA narrative on kratom has become a rallying call for plaintiff's attorneys to actively recruit anti-kratom advocates to directly contact the FDA to report alleged kratom adverse events. As on example, a group calling itself Kratom Danger Awareness (KDA) had an offer from a plaintiff's attorney to provide $1 million to support their efforts, which included a campaign to report adverse events allegedly related to kratom use. These kinds of advocacy efforts are not uncommon, but when the FDA becomes the unwitting partner in such efforts without applying the requisite rigorous examination of the facts of any such reports, the casualty is both the loss of the integrity of the FDA's adverse event reporting system, and the overall credibility of the FDA in fulfilling its statutory duty to be an unbiased steward protecting the health and safety of Americans.

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[10] See: https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-not-use-optimized-plant-mediated-solutions-opms-black-liquid-kratom (last accessed August 28, 2024).

Conclusions:

The AKA respectfully requests that the FDA convene a public stakeholders meeting dedicated to the discussion of kratom products. Such a meeting would provide an invaluable opportunity for the FDA to engage directly with the kratom consumers most affected by potential regulatory actions, to hear from scientific and policy experts who have studied kratom, to evaluate legal experts views on the current excesses of the FDA's abuse of authority in regulating kratom, and to better understand the experiences of those who use kratom as part of their health regimen as evidenced by numerous peer-reviewed published articles supporting the claims by consumers that kratom is helping them improve the quality of life they experience and, in many cases, actually saving their lives.

The stakes are high, and the outcomes of FDA-regulatory decisions pertaining to kratom products will have profound impacts on many lives. A public stakeholders meeting would help to ensure that these decisions are made with a full understanding of the potential benefits and risks, and that they are guided by current science, compassion, and a commitment to public health.

I appreciate your attention to this matter and look forward to your response. Thank you for your continued dedication to protecting and promoting the health of the American public.

Sincerely,

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