AMERICAN KRATOM ASSOCIATION

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American Kratom Association: FDA disregards the will of Congress and disrespects American public in comment process for World Health Organization

Announces webinar briefing 8PM, Wednesday, August 25

WASHINGTON, D.C. – August 24, 2021 - The American Kratom Association (AKA) today released the following statement regarding the end of the Food and Drug Administration's (FDA) comment period on a potential international ban by the World Health Organization (WHO) on kratom, an herbal supplement used by millions of Americans as an energy supplement and for pain management, specifically as an alternative to opioids and for opioid addiction treatment:

"The FDA's conduct regarding WHO's potential ban of kratom is an incredible disappointment to the millions of Americans whose lives have been changed for the better by kratom, a non-addictive herbal supplement that has shown incredible promise as an opioid alternative and an effective treatment for those battling opioid addiction. In 2016, Americans made their voices heard and successfully defeated FDA's attempt to criminalize the use of kratom. Congress has repeatedly reaffirmed the will of the people, most recently just one month ago, when the U.S. House passed spending bills with language that supported kratom as an alternative to opioid therapy and funded more kratom research.

"It seems at almost every turn, the FDA has tried to stifle the voices of kratom advocates, via conflicting directions, an uncharacteristically short comment period, and numerous hurdles to get comments accepted. FDA's actions disregard the will of Congress and disrespect the American public who have spoken resoundingly in favor of kratom. Despite these barriers, we have collected more than 60,000 comments before the FDA's deadline with plans to continue submitting comments until the WHO's deadline on September 24. We are working with numerous partners in Congress to ensure that Americans' voices are heard and that any effort from the World Health Organization to prevent the manufacturing and distribution of kratom is stopped once and for all.

"Too many American lives have been improved by kratom – with many more standing to benefit – for us to now stifle or completely ban its use in the United States. We are grateful for the many scientists, experts, lawmakers, and everyday Americans who have helped us through this

process, and we are hopeful that the resounding support for this incredible herbal supplement will be recognized, and a ban will ultimately be opposed." Mac Haddow, Senior Fellow on Public Policy at the AKA.

The AKA will host a webinar briefing Wednesday, August 25 at 8PM to discuss next steps required to stop an international kratom ban. Participants may register at https://us02web.zoom.us/webinar/register/WN_0rAOUtllSj-8MirEh8e8uA

Press should include their name and media outlet for the zoom call.

Following is background related to the FDA's inappropriate handling of comments and potential consequences of FDA's misguided actions:

- The FDA received notice of the proposed WHO Expert Committee pre-review of kratom on June 10, 2021 but delayed the required Federal Register Notice soliciting public comments for 42 days until July 23.
- When FDA finally announced a comment period, they only provided a 17-day window (11 business days) for scientists and the public to prepare and submit comments. Not only is that an unreasonable length of time but also a violation of requirements dictated by the Controlled Substances Act and procedural safeguards of the Administrative Procedures Act. It is also a stark departure from the typical 30 to 60-day comment period that FDA permits on such matters.
- In order to guarantee a fair process and reasonable comment window, AKA filed a lawsuit to extend the comment period and won.
- To comply with the lawsuit, FDA reopened the comment portal, but their website was no longer setup to receive comments directly, instead pointing people to a different website which created confusion and established a barrier to public input.
- At the recommendation of an FDA representative, the AKA attempted to hand deliver comments on August 9, but no staff were present to receive them. When the AKA Executive Director called the FDA, a representative said to redeliver the next day (past the deadline) or to submit electronically.
- The AKA submitted nearly 40,000 comments electronically, per FDA's instructions, yet so far, receipt of comments has not been acknowledged by FDA or recorded publicly.

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ABOUT AKA

The American Kratom Association (AKA), a consumer-based non-profit organization, is here to set the record straight about kratom and gives a voice to the millions of Americans who safely consumer kratom each year. Kratom is a plant mainly grown in Southeast Asia that is helping millions of Americans better manage their overall health and well-being.