



LEADING SCIENTISTS STRONGLY REJECT FDA 8-FACTOR ANALYSIS OF KRATOM CALL UPON THE DEA AND NIDA TO REEXAMINE FDA CLAIMS

American Kratom Association Requests FDA to Retract Kratom Scheduling Recommendation

[Leading scientists¹ have made public a 33-page letter](#) they have sent to the heads of the U.S. Department of Health and Human Services (HHS), the U.S. Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and the National Institute on Drug Abuse (NIDA) expressing strong objections to methodology and lack of scientific rigor of the FDA's 8-Factor Analysis (8 FA) of kratom.

Among multiple questions raised by the scientists—led by Dr. Jack Henningfield, Vice President of Research, Health Policy, and Abuse Liability at Pinney Associates—the team expressed concern about the omission of key data sources, highlighting areas where the FDA's conclusions were not reliable, valid, or complete. According to the scientists, the FDA analysis also failed to include evidence or input from NIDA or kratom science experts.

“These preeminent scientists have demonstrated that the FDA is a long way away from providing sufficient analysis of kratom to back up its recommendation that this natural botanical be listed as a Schedule I substance,” said David Herman, Chairman of the American Kratom Association.

Herman referenced the fact that the full FDA 8-Factor Analysis actually has yet to be made public and that several pages have been omitted in what the FDA claims to be an accidental release. “This whole process raises more questions than answers,” said Herman. “However, there is sufficient information in what the FDA has released to reflect that they did not engage in a comprehensive, scientifically-based process, but rather what appears to be an exercise to reinforce its fight against kratom.”

[In their letter](#), the scientists call upon the DEA, in conjunction with NIDA, to transparently reexamine the FDA's claim of abuse potential related to kratom and propose regulatory alternatives to its scheduling. Part of that evaluation should include a survey that helps the government better understand how kratom is consumed in the United States. The letter also

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calls on the FDA to work with industry groups—such as the American Kratom Association, who have developed [Good Manufacturing Practices](#) that lead to safe manufacturing standards that will help keep harmful byproducts out of kratom—to develop regulations that cover the manufacturing of kratom products.

The American Kratom Association adds its voice that the DEA must send this issue back to the FDA to fully reexamine the data, analysis, and conclusions regarding kratom.

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

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