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AMERICAN KRATOM ASSOCIATION

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American Kratom Association Issues Consumer Advisory on FDA's Failure to Properly Regulate Kratom that Result in Product Liability Lawsuits

Recent court decisions on alleged kratom deaths are the result of a combination of FDA's failures to regulate kratom products and aggressive trial attorney actions that fail to hold the FDA accountable for their lack of regulations.

WASHINGTON, D.C., UNITED STATES, July 31, 2023 – The American Kratom Association (“AKA”) issued a Consumer Advisory on the FDA’s failure to properly regulate kratom products:

1. The American Kratom Association urges the FDA to immediately publish product manufacturing standards for kratom products that are sold to consumers and encourages the removal of kratom products that do not provide adequate labeling instructions: including recommended serving sizes and product ingredient listings, and appropriate warnings on conditions of use.
2. Until the FDA implements a rational set of standards to protect consumers, the AKA advises kratom consumers they should not purchase or consume kratom products that:
 - a. Have not been certified by an independent third-party lab to be free of dangerous contaminants or contains adulterants that could be dangerous to consume.
 - b. Are offered for sale from a vendor that markets its product with illegal therapeutic claims.
 - c. Do not contain the name of the product distributor so that a consumer can file an adverse event report if required.
 - d. Are delivered in unprofessional packaging, i.e., zip lock bags, product information written with a pen or sharpie, or handwritten product information.

“The FDA’s irresponsible war on kratom and the Agency’s refusal to implement product manufacturing and marketing standards has led to the marketing of dangerous kratom products exposing consumers to unacceptable risks,” explained Mac Haddow, Senior Fellow on Public Policy. “Recent reports of product liability awards for irresponsibly manufactured or marketed kratom products are the direct result of the FDA’s complete failure to regulate the kratom marketplace and, in some cases, the exploitive behavior of trial attorneys who do nothing to compel the FDA to act responsibly.”

Based on a review of the litigation reports, the product liability awards by the courts have been based on the failure of the product manufacturers to provide labeling instructions for responsible use and little or no information on the contents of the potentially adulterated products. The FDA has failed to publish any good manufacturing practices guidelines and has failed to require proper labeling or marketing. The AKA has submitted more than 75 documented complaints of kratom manufacturers using illegal therapeutic claims for kratom products, and the FDA has not prosecuted a single case in 3 years. Here is an example of a kratom product that a court found the vendor to be liable. If the FDA was doing their job, this product would not have been on the market.



Talavera's fiancé found her lying unconscious next to a packet of powder with "Space Dust" scrawled on it. The powder turned out to be a concentrated kratom extract.

U.S. District Court, Southern District of Florida

“The safety and addiction profile of pure, unadulterated kratom is well-documented by science and there is no known level of kratom use that would cause any fatality unless it is irresponsibly consumed, adulterated with a toxic drug, or used in concurrently with a deadly drug substance,” Haddow continued. “The consumer is caught in the trap between the FDA who refuses to act on its duty to responsibly regulate kratom, and some trial attorneys who benefit financially from the lack of FDA regulation on kratom.”

The AKA supports congressional action to compel the FDA to develop and implement a set of standards for the manufacturing and marketing of kratom products to protect consumers in the United States.

ABOUT AKA

The American Kratom Association (AKA), a consumer-based, nonprofit organization, focuses on setting the record straight about kratom and gives a voice to those who are suffering by protecting their rights to possess and consume safe and natural kratom. AKA represents millions of Americans, each of whom has a unique story to tell about the virtues of kratom and its positive effects on their lives.

For more information, visit www.AmericanKratom.org, www.Kratomanswers.org or www.Protectkratom.org. Follow them on Twitter (@TheKratomAssn), Facebook (<https://www.facebook.com/Americankratomassociation/>)