



DENIED

FDA REVIEW: KRATOM NOT SHOWN TO BE SAFE AS A DIETARY SUPPLEMENT

Regulatory Determination (Most Important Findings)

- FDA could not conclude kratom is reasonably safe
- Insufficient evidence to rule out a “significant or unreasonable risk of illness or injury”
- Product may be legally considered adulterated under federal law
- Interstate sale of such products is prohibited under the FD&C Act

CRITICAL SCIENTIFIC FAILURES IDENTIFIED BY FDA

- Identity and composition could not be established
- FDA could not verify what the product actually contains
- Safety data inadequate to support use—even at proposed low doses (50 mg/day)
- Submitted evidence failed to demonstrate consumer safety

Regulatory Conclusion

Kratom failed to meet the federal safety standard for dietary supplements—FDA found the evidence insufficient to establish safety and determined such products may be *adulterated* and illegal to introduce into interstate commerce.

Learn More at antikratom.org

Source: U.S. Food and Drug Administration — NDI Review (Johnson Foods, Jan 4, 2023)