

FDA: Kratom Not Proven Safe for Use

Kratom (*Mitragyna speciosa*) is not approved as a drug, dietary supplement, or food additive in the U.S.



KEY FDA DETERMINATIONS

Not FDA-Approved

No approved drug products containing kratom
Not lawfully marketed as a supplement or food

Opioid Receptor Activity

Mitragynine and 7-OH bind to mu-opioid receptors

Potential Adverse Effects

Sedation, respiratory depression, dependence, and withdrawal reported

Contamination Risks

FDA has identified products contaminated with Salmonella and heavy metals.

Kratom products are widely available in the U.S., but FDA has determined there is insufficient evidence to establish safety for use as a dietary ingredient.

FDA has warned consumers about serious risks, including liver toxicity, seizures, and substance use disorder.


Public Health Concerns

- No standardized dosing or product consistency.
- Documented dependence and withdrawal
- Limited well-controlled human studies
- Active federal enforcement actions

FDA: Kratom safety has not been established and remains a public health concern.

No FDA-approved uses. Safety not established.

For more information

 www.antikratom.org

Sources U.S. Food and Drug Administration — Public Health Advisories on Kratom (2023–2025)