

## POLICY BRIEF

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# Kratom is a Food

When kratom is sold or used as a food product it does not require approval by the U.S. Food and Drug Administration (FDA) prior to sale or use, and FDA's assertions about kratom being an unapproved dietary supplement, a food additive, or an unapproved drug as the gateway for the Agency's expansion of its regulatory authority are not supported by federal laws, rules, guidance, or enforcement actions.

There are between 11 and 16 million kratom consumers in the United States who regularly consume kratom to enhance well-being, for increased energy and stamina for work, for increased focus for daily activities, and to reduce anxiety and depression. Consumers also report choosing to use kratom to help them abstain from the use of other potentially more harmful substances.

Importantly, consumers report they choose to use kratom as a natural home remedy preferred to other options, including conventional medicines, because of its low rate for adverse events and its relative safety.

In 2016, FDA unsuccessfully recommended the scheduling of two of kratom's alkaloids, mitragynine and 7-hydroxymitragynine, to the Drug Enforcement Administration (DEA) and has made a second scheduling recommendation that was filed in November 2017 that the DEA has not acted on. In the interim, emerging science clearly demonstrates that kratom is not a candidate for scheduling under the scheduling criteria set forth in the Controlled Substances Act (CSA).

The FDA has failed to meet its burden on the specific criteria required under the CSA to justify its scheduling recommendation, and the evidence the FDA cites in the documentation for scheduling has been discredited as inaccurate, outdated, or plainly not applicable to kratom and its alkaloids.

FDA has attempted to circumvent the CSA scheduling process by imposing Import Alerts on kratom raw materials exported to the United States from Southeast Asia. The Congress clearly did not intend to give

### KEY FINDINGS

Kratom sold as a food product does not require FDA approval and the FDA has acknowledged they do not have authority over the premarket approval of food products.

Between 11 and 16 million Americans safely consume kratom products as a preference to conventional medicines because of its low rate for adverse events and its relative safety.

The DEA holds the exclusive authority to schedule all harmful substances, and they have not accepted the FDA's repeated scheduling recommendations on kratom.

The FDA currently has sufficient authority to regulate adulterated and contaminated kratom products to protect consumers, and they should use that authority where needed.

The FDA can enforce current laws against any kratom marketer who makes illegal therapeutic claims about kratom that may mislead consumers for their own economic gain.

FDA the power to create a de-facto total ban on any product that does not meet the criteria for scheduling under the CSA. In the instance of kratom, virtually all kratom raw material originates in Southeast Asia and FDA exploits that fact to abuse its Import Alert power to create a new regulatory ban on kratom that Congress intended should be determined exclusively by the DEA.

The American Kratom Association (AKA) strongly supports FDA enforcement action on any unscrupulous kratom marketer labeling products with illegal therapeutic claims that mislead consumers into purchasing those products. The AKA also supports an appropriate regulatory scheme to assure kratom products are manufactured according to GMP standards for food products to protect consumers.

### **How FDA Regulates Kratom:**

FDA regulates a product based on its intended use as evidenced by the product's labeling and claims.<sup>1</sup> Kratom, like other products intended to be a food, dietary supplement, or cosmetic, do not require FDA approval.<sup>2</sup> FDA has acknowledged it "does not have premarket approval of food products."<sup>3</sup>

Instead, FDA can approve certain ingredients before they are used in foods such as food or color additives.<sup>4</sup> As such, kratom that is intended to be a food, and not a food or color additive, is not a product that FDA approves.<sup>5</sup> Therefore, it can be legally marketed as such. In addition, when intended for use as a food, it is immaterial that kratom does not have any "approved uses," since food products are not "approved."<sup>6</sup>

FDA has the legal authority to take regulatory action against a manufacturer, distributor, or vendor of a food product that is adulterated under the standards set forth in the Food, Drug and Cosmetic Act. It may do so if a food product "bears or contains any poisonous or deleterious substance which may render it injurious to health, or the food is a dietary supplement or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling."<sup>7</sup> If FDA finds a food product adulterated, the Agency may take enforcement action against a kratom company through issuing Warning Letters, Untitled Letters, 483 Inspection Observations, and Recalls.<sup>8</sup>

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<sup>1</sup> See *Small Entity Compliance Guide on Structure/Function Claims*, 67 Fed. Reg. 1225, Jan. 9, 2002, available at <https://www.federalregister.gov/documents/2002/01/09/02-451/small-entity-compliance-guide-structurefunction-claims-availability>.

<sup>2</sup> Unlike those products, FDA requires premarket approval of drugs and many medical devices.

<sup>3</sup> *Is It Really "FDA Approved?"* FDA.gov, January 2017, available at <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved#:~:text=FDA%20approves%20food%20additives%20in,to%20food%2C%20and%20color%20additives>.

<sup>4</sup> *Id.*

<sup>5</sup> A food additive includes "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly ... in its becoming a component or otherwise affecting the characteristics of any food." 21 C.F.R. § 570.3. Food means "articles used for food or drink for man." 21 U.S.C. § 321. Kratom does not meet an additive definition, because kratom is itself the food, not the additive.

<sup>6</sup> Although premarket approval is not required, food products are regulated by FDA. For example, manufacturers at a minimum must meet Good Manufacturing Practices, have proper labeling, and register as a food facility.

<sup>7</sup> This list is not an exhaustive list. 21 U.S.C. § 342; *Questions and Answers Regarding Mandatory Food Recalls*, FDA Guidance, November 2018, available at <https://www.fda.gov/media/117429/download>.

<sup>8</sup> See *generally Compliance & Enforcement (Food)*, FDA.gov, available at <https://www.fda.gov/food/compliance-enforcement-food>.

FDA has never found that all kratom products are adulterated.<sup>9</sup> As with other food products, FDA has taken specific enforcement action against specific kratom manufacturers if they have been found to market kratom as an unapproved drug, or due to particular public health risks. Specifically, FDA has issued Warning Letters to a number of kratom companies for making unproven medical claims, including opioid treatment claims.<sup>10</sup>

FDA has also issued a voluntary and mandatory recall to a number of kratom manufacturers in 2018 due to a salmonella outbreak.<sup>11</sup> The Centers for Disease Control and Prevention (CDC) reports that *salmonella* is a bacteria that commonly causes foodborne illness, sometimes called “food poisoning.” CDC estimates salmonella causes 1 million foodborne illnesses every year in the United States. During the past few years, outbreaks of salmonella illness have been linked to contaminated cucumbers, pre-cut melon, chicken, eggs, pistachios, raw tuna, sprouts, and many other foods.<sup>12</sup>

FDA presently has sufficient regulatory authority to require any kratom product contaminated with salmonella to be removed from the marketplace. Kratom vendors now regularly test for salmonella contamination in imported kratom raw materials and the risk to the public has been substantially reduced. It is substantively the same approach that vegetable and fruit importers use to minimize the risks to the public from such contamination.

## **Conclusion:**

Kratom can be lawfully marketed and sold as a food. FDA does not preapprove food products. Although FDA has taken enforcement action against kratom manufacturers and vendors whose products are intended to be used for other purposes such as an unapproved new drug, the Agency has never found that all kratom is adulterated. To the contrary, kratom has been lawfully and safely consumed as a food by American consumers for decades.

The FDA can and should enforce all labeling laws that restrict the sale of kratom where a marketer makes an illegal therapeutic claim. The AKA maintains a “Truth in Labeling” program to support the responsible sale of kratom products and the referral of any non-compliant violators to the FDA for enforcement actions.

Millions of Americans eat or drink kratom every day to improve their well-being. Kratom can be legally sold under existing FDA laws, rules, and guidance.

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<sup>9</sup> FDA has issued two import alerts related to kratom—one regarding dietary supplements (Import Alert 54-15) and one regarding unapproved new drugs (Import Alert 66-41). Neither is at issue here. Moreover, these import alerts apply to importers and not to a domestically manufactured, distributed, or sold kratom in the United States.

<sup>10</sup> Manufacturers may not lawfully make medical claims about a food product such as that the product prevents, treats or mitigates a disease or illness without FDA approval. See e.g., *Cali Botanicals, LLC Warning Letter*, FDA.gov, June 2019, available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cali-botanicals-llc-575320-06112019>; *KratomNC Warning Letter*, FDA.gov, June 2019, available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kratomnc-576964-05162019>.

<sup>11</sup> *FDA orders mandatory recall for kratom products due to risk of salmonella*, FDA.gov, April 2018, available at <https://www.fda.gov/news-events/press-announcements/fda-orders-mandatory-recall-kratom-products-due-risk-salmonella>.

<sup>12</sup> <https://www.cdc.gov/foodsafety/communication/salmonella-food.html>