The FDA has warned consumers not to use kratom because of its concern that this botanical "appears to have properties that expose users to the risks of addiction, abuse, and dependence."[2] FDA Commissioner Gottlieb has expanded on this position by stating the compounds found in kratom are "opioids."[3] The FDA has widely circulated this position that kratom and its alkaloids have the same effect as opioids, and that characterization has created significant policy questions related to pending legislation on Capitol Hill addressing various elements of the ongoing opioid crisis in America.

In addition, the FDA claims there are 44 reported deaths associated with the use of kratom.[4] The FDA has also embraced a novel computational model to conclude that two of the top five most prevalent compounds in kratom are known to activate opioid receptors (opioid agonists) in the brain. The FDA also claims it has completed and submitted the required 8-Factor Analysis to justify its recommendation to the Drug Enforcement Administration (DEA) for kratom to be a Schedule I substance effectively banning it from consumer access and significantly limiting needed research on potential kratom uses.

AKA Response:

The AKA believes the FDA position on kratom materially misstates the purported public safety risks associated with the use of kratom. The AKA believes it is very important to distinguish between products derived from the botanical plant (kratom) and manufactured under FDA regulations and guidelines -- as opposed to adulterated and/or contaminated kratom products. It is equally critical to distinguish between opioid agonists that do activate opioid receptors in the brain and then subsequently suppresses the respiratory system of the user – as opposed to partial agonists like the alkaloids of kratom that activate opioid receptors but have no measurable impact on a user's respiratory system.

In addition, the AKA believes it is essential to differentiate between adverse medical events and deaths where the decedent died from polydrug use, use of contraindicated prescription medications, or underlying medical conditions that may have been the actual cause of the death while also using a kratom product. In this context, there is not a single death or adverse event that can be fairly evaluated as having been caused by kratom.

As a statement of principles related to the safe use of kratom products, the AKA submits the following as a baseline for its AKA GMP-Certification Program:

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[2] FDA and Kratom, U.S. Food and Drug Administration, https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm584952.htm

[3] Statement from FDA Commissioner Scott Gottlieb, M.D. on the agency's scientific evidence on the presence of opioid compounds in kratom, underscoring its potential for abuse, U.S. Food and Drug Administration, February 6, 2018, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm595622.htm

[4] *Ibid.*

- Kratom suppliers should be subject to all applicable FDA GMPs on the manufacture of kratom products as set forth in 21 CFR Part 111.
- Consumers should have access to clear labeling of all kratom products as set forth in the Dietary Supplement Labeling Guide published in April 2005 (and any subsequent guidance),[5] and AKA supports additional labeling instructions that advise against use by children under the age of 18, or use by pregnant women.
- The labeling on kratom products should specifically state the levels of the two alkaloids of specific concern to the FDA, mitragynine and 7-hydroxymitragynine, and any appropriate warnings on the appropriate amounts that can be safely consumed by a consumer.
- The AKA supports the FDA using its regulatory powers to seize and recall any kratom product associated with an impermissible health claim as set forth in FDA Guidance on label requirements in prevailing FDA regulations.[6]
- The AKA supports the FDA using its regulatory powers to interdict any adulterated or contaminated kratom products that contains a banned substance or that enhances, refines, or concentrates the alkaloids in the kratom plant by initiating product seizure, recalls, and appropriate criminal and civil prosecution of responsible parties.[7/8]

The AKA believes the science supports the proposition that the FDA should rescind the current Import Ban on the botanical kratom plant in leaf, powdered, or acceptable extract form, and replace it with an Import Alert on any kratom product that is adulterated and/or contaminated with another substance that fails to meet FDA GMPs set forth in 21 CFR Part 111.

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[5] Dietary Supplement Labeling Guide: Chapter I. General Dietary Supplement Labeling, U.S. Food and Drug Administration, April 2005, https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm070519.htm#1-2

[6] Guidance for Industry: FDA Implementation of "Qualified Health Claims": Questions and Answers; Final Guidance, May 12, 2006, https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053843.htm

[7] Memorandum of Understanding with the Department of Agriculture and the Food and Drug Administration, 40 Fed. Reg. 25079 (June 12, 1975) (agreement concerning related objectives in carrying out the Federal Meat Inspection Act, Poultry Products Inspection Act, and the Federal Food, Drug, and Cosmetic Act).

[8] 21 U.S.C. §§301 et seq.