AMERICAN KRATOM ASSOCIATION

POLICY REPORT

Establishment of the American Kratom Association GMP-Certification Program to set standards for operations and conduct of businesses who produce kratom products for consumers

COMMITMENT TO PROTECT KRATOM CONSUMERS

The American Kratom Association (AKA) is committed to ensuring the manufacturing and supply chain of kratom products intended for use by consumers are compliant with applicable FDA regulations and guidelines governing food and dietary supplements.

AKA strongly affirms its commitment to promote quality standards and adherence to the FDA good manufacturing processes specific to dietary supplements as set forth in 21 CFR Part 111, and applicable labeling requirements that meet or exceed current FDA regulations and guidelines for such products.

The AKA, in order to bring order to and restore consumer confidence in the supply chain for kratom products, has established the AKA GMP-Certification Program to (1) provide kratom manufacturers with specific standards for production and marketing of products to ensure the safety for use; and (2) provide consumers with a list of companies who demonstrate a commitment to a high level of compliance to the AKA GMP Standards as verified through comprehensive third-party inspections and GMP-related documentation.

PROGRAM OVERVIEW

In an effort to increase consumer safety, and restore consumer confidence in the supply chain of kratom products, the AKA GMP-Certification Program will identify kratom manufacturers and vendors who document and agree to third-party verification inspections and GMP-related documentation to verify compliance with the requirements of the AKA GMP standards. The AKA will publish a list of suppliers who have certified compliance with the standardized set of GMPs set forth in the AKA GMP-Certification Program and who are authorized to use the AKA GMP Certification Seal of Approval on their product packaging. The AKA will regularly promote this list of suppliers who meet these standards to provide consumers with a higher level of confidence in the kratom products they seek to purchase.

The AKA GMP-Certification Program will ensure that kratom product manufacturing and/or packaging processes are adequately controlled so that all products meet the established specifications for quality, ingredient identity, purity, strength, and appropriate labeling of such products. To maintain the AKA GMP Seal of Approval status,

suppliers must maintain compliance to the AKA GMP-Certification Program standards and terms of certification, including required third-party audits.

A key element of the AKA GMP-Certification Program is the independent third-party auditing function that verifies a supplier's compliance with program standards. The AKA will identify qualified auditors who have demonstrated their ability and qualifications to conduct on-site independent audits and inspections of food or dietary supplement manufacturers. The auditor will inspect all facilities that conduct manufacturing, testing, packaging, labeling, storage and/or distribution of kratom products to ensure that all elements of the manufacturing processes are analyzed and evaluated to provide assurances that appropriate processes are in place and sufficiently controlled so the kratom products meet their established specifications for quality related to the safety with respect to purity, strength and composition. The Auditors will then provide their report to AKA for its review and assessment of the application or ongoing participation in the AKA GMP-Certification Program.

The AKA will also establish a GMP Working Group, comprised of individuals with expertise and knowledge with GMPs of dietary supplement and food products, to oversee the AKA GMP-Certification Program and to provide guidance on ongoing enhancements and procedures that are required to maintain the mission to ensure the safety of the kratom product supply chain.

PUBLIC POLICY CONSIDERATIONS

Background:

The FDA has embarked on a broad policy and public relations campaign to ban kratom and deny consumer access to kratom products. In addition to concerns about the safety of kratom for consumer use, the FDA has also determined that kratom is being used by a significant number of individuals for unapproved medicinal purposes, including as an alternative opioid pain management therapy to opioids or as a substance to step down from an opioid addiction.

The FDA placed an Import Alert on kratom in 2012, and then reaffirmed that Import Alert in 2014 and 2016. The impetus for the initial Import Alert followed reports of 9 deaths that occurred in Sweden over a 12-month period in 2009 that was attributed to a kratom powdered product sold on the Internet known as "Krypton."[1]

[1] Notice of Intent, Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine Into Schedule I, Department of Justice, Drug Enforcement Administration, Docket No. DEA-442, August 31, 2016, https://www.deadiversion.usdoj.gov/fed_regs/rules/2016/fr0831.htm

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.