AMERICAN KRATOM ASSOCIATION

BASELINE FOR GMP STANDARDS IN THE MANUFACTURING OF KRATOM PRODUCTS

The American Kratom Association (AKA) provides the following baseline recommendations for GMP standards for the manufacture and distribution of kratom products. These recommendations will be presented to independent experts for review and evaluation. The final report from these experts will be published no later than August 15, 2018, after which AKA will organize compliance training programs for kratom manufacturers and vendors to assist in the production and distribution of safe kratom products for consumers.

AKA cGMP Program

- As a minimum baseline for the production of kratom products, the following standard procedures that govern the operations and conduct of a business in the kratom industry should be immediately adopted and followed. These standards serve to outline all aspects of business operations and marketing as it relates to the safety and quality of the material being provided by kratom producers and resellers, and enhancements will be submitted as they are adopted by the AKA GMP Working Group.
    - Standards / Standard operating procedures
        - Personnel compliance training
        - Record keeping -- all records should be kept in a manner and standardized form so that operations can be audited by an independent 3rd party.
            - Master Batch Record / Batch production records will be kept for each product.
            - Material Traceability
                - Full chain of custody and master records for all purchased and sold items with standard double verification (e.g., a packer sign-off and QC manager sign-off)
                - Implementation of a supply chain system that allows a vendor to determine which customers received a given batch and from whom that batch of material was initially supplied by
        - Process of receiving material, quarantine, production / processing, packaging, storage and sale (all of this would be done on a per-batch basis)
        - Cleaning and sanitation of storage / production / processing / areas along with inspection of other contact surfaces or areas exposed to material.
        - Verification of cleaning and sanitization by swab test approved by FDA.

- True randomized sampling for analysis to a degree that would ensure a very low probability of an undetected contaminant.
- Material analysis / Qualification by an independent 3rd party lab analytical firm to monitor:
    - Biological contaminants
    - Heavy metals
    - Chemicals
    - Synthetic drugs
    - Shelf life testing
- Process of qualifying and disqualifying a supplier.
- Establishing what a batch is and what constitutes a "different" batch.
- Receiving and initial quarantine of materials until all tests and analysis are complete and all pass the established specs. Implementation of rejection protocol.
- Adverse Event Reporting System to monitor the following:
    - Consumers who experience an adverse health event related to a kratom product
    - Contaminated / Adulterated products (must have evidentiary requirements, ex. tests of a product / secondary confirmation, etc.)
    - Vendors selling counterfeit / tainted / adulterated products
    - Vendors manufacturing / selling products that are supported by health claims

Marketing Practices

- No impermissible health claims allowed in any marketing programs.
- No structure or function claims.
- No reference to research or any clinical data.
- Labels require the disclosure of Mitragynine and 7-OH alkaloid content.
- A Batch / Lot # required on every individual product packages.
- Labels must advise users to consult with a physician for dosing information relative to alkaloid values.
- No kratom products should be sold to individuals under the age of 18. Pregnant women are encouraged not to use kratom products during their pregnancy.
- All marketing materials and labels will include the following FDA Warning: "This product is not intended to diagnose, treat, cure, or prevent any disease or condition."