        - The identity of the equipment and processing lines used in producing the batch;
        - The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to such records, such as individual equipment logs, where this information is retained;
        - The unique identifier assigned to each component, packaging, and label used;
        - The identity and weight or measure of each component used;
        - A statement of the actual yield and a statement of the percentage of theoretical yield at each phase of processing;
        - The actual results obtained during any monitoring operation;
        - The results of any testing or examination performed during the batch production, or a cross-reference to such results;
        - Documentation that the finished product meets the specifications established for the product;
        - Documentation, at the time of performance, of the manufacture of the batch, including the date on which each step of the master manufacturing record was performed and the initials of the persons performing each step of the master manufacturing record; the packaging and labeling operations; and review by quality control personnel.
- Traceability
    - Maintain records of the full chain of custody and master records for all purchased and sold items with standard double verification (e.g., a packer sign-off and Quality Control manager sign-off).
    - Establish and implement 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.

Adverse Event Reporting System and Recalls

- Establish and implement a written Adverse Event Reporting System to:
    - Review all product complaints to determine whether the product complaint involves a possible failure to meet the specifications for the product, or any other requirement in these standards or 21 C.F.R. Part 111 that, if not met, may result in a risk of illness or injury;
    - Investigate any product complaint that involves a possible failure of a product to meet any of its specifications, or any other requirement in these standards or 21 C.F.R. Part 111 that, if not met, may result in a risk of illness or injury;
    - Monitor consumers who experience an adverse health event related to a kratom product;
    - Monitor potential contamination or adulteration of kratom products;
    - Monitor vendors selling counterfeit, contaminated, or adulterated kratom products; and
    - Monitor manufacturers or distributors of kratom products using health claims.
- Recalls
    - Establish and implement a written recall procedure and conduct mock recalls according to the procedure.

Marketing Practices

- Labeling and Advertising
    - The labels, labeling, or advertising of any kratom product should not bear any disease claims (i.e., claims regarding the treatment, cure, prevention, or mitigation of disease) or unauthorized health claims.
    - The labels, labeling, or advertising of any kratom product should not bear any structure/function claims.
    - The labels, labeling, or advertising of any kratom product should not reference any research or clinical data.
    - Each finished product label must include a batch or lot number.
    - Each finished product should be labeled to disclose the mitragynine and 7-OH alkaloid content of the product.
    - Each finished product label must advise consumers to consult with a physician for dosing information relative to alkaloid values.
    - No kratom products may be sold to individuals under the age of 18.
    - The label should bear a statement that pregnant women should not use kratom products during pregnancy.
    - All labels, labeling, or advertising should include the following statement: "This product is not intended to diagnose, treat, cure, or prevent any disease or condition."

Compliance

All AKA Member Companies are strongly encouraged to adopt these standards and to implement an effective compliance program – one which includes policies and procedures that foster compliance with the standards. A Company that adopts this code is strongly encouraged to submit to AKA a certification that the Company has adopted the code and has implemented an effective compliance program. AKA will publish on its website a list of those Companies that have submitted this certification and have had their certification verified by an independent third-party auditor using these standards.

Next Steps

Over the next 60 days, the AKA will identify and train 3rd party auditors on the GMP Certification Program. This 60-day window will give vendors an opportunity to refine existing processes and/or implement new ones.

The AKA will be conducting several "Training Webinars" to answer any questions and provide updates or new information. The webinars will be conducted on the following dates:

- Thursday, August 30, 7:00pm ET
- Thursday, September 6, 7:00pm ET
- Wednesday, September 26, 7:00pm ET

Invitations will be sent out with the necessary call-in information.

If you have any questions or would like to participate in the AKA GMP Certification Program, please contact Sherry Chlebowski at sherry@americankratom.org.