AMERICAN KRATOM ASSOCIATION

AKA Good Manufacturing Practice (GMP) Certification Program

Preamble

The American Kratom Association (AKA) is establishing this program to assure the safety and integrity of kratom dietary supplements that are marketed in the United States. The program establishes exacting manufacturing, labeling, and verification requirements for kratom dietary supplements that go well beyond the minimum requirements for manufacturing dietary supplements established by the U.S. Food and Drug Administration (FDA). For example, companies participating in this program will need to test every production lot of kratom to assure it is free of any microorganisms of public health concern, disclose the quantity of the mitragynine and 7-OH alkaloid in the product, and agree to annual audits of their facility and programs.

Companies that voluntarily participate in this program will be required to have their facility audited by an independent 3rd party that will verify the company is in compliance with the Food and Drug Administration (FDA) good manufacturing practices for dietary supplements and the additional requirements established under this program. These standards serve to outline all aspects of business operations and marketing as it relates to the safety and quality of material being provided by kratom producers and resellers, and enhancements will be submitted as they are adopted by the AKA GMP Working Group. The exacting standards established in this program are designed to restore consumer confidence in kratom dietary supplements. Dietary supplements that meet the exacting standards of this program will be listed on the AKA website [and will be eligible to bear the "AKA Certified" seal on their label].

AKA GMP Standards for Manufacturing of Kratom Products

Any company participating in this AKA program must have an annual 3rd party audit documenting compliance with the FDA dietary supplement GMPs found at 21 CFR Part 111.[1] AKA will maintain a list of auditors that are (1) qualified through training and experience to conduct dietary supplement GMP audits and (2) are able to audit against the criteria in the AKA program. Companies participating in this program must have annual audits of their facilities documenting compliance with the Dietary Supplement GMPs and this AKA program.

The auditors are trained to focus particular attention on the company's ability to implement the following provisions of the dietary supplement GMPs. Any company that fails to have adequate programs addressing these aspects of the GMPs will receive a failing grade and will be ineligible to participate in this program.

[1] 21 C.F.R. Part 111 is available at: https://www.ecfr.gov/cgi-bin/text-idx?SID=8b3eb269ea843cecfb7555bf5634d110&mc=true&node=pt21.2.111&rgn=div5.

Standard Operating Procedures

- Personnel
  - Establish and follow written procedures to prevent microbial contamination from sick or infected personnel and for hygienic practices at the facility.[2]
  - Establish and implement a personnel compliance training program. Maintain documentation of the training.
- Manufacturing Facility and Equipment
  - Establish and implement procedures to ensure the facility is in a condition that protects against the contamination of ingredients, finished products, and contact surfaces.[3]
  - Clean and sanitize storage, production, processing, and packaging areas according to an established schedule. Verify the effectiveness of cleaning and sanitation operations by conducting swabbing of contact surfaces according to an established schedule and sampling plan.
- Manufacturing Operations
  - Establish and implement written procedures for the processes of (1) receiving material; (2) quarantine; (3) production/processing; (4) packaging; (5) storage and sale. Maintain records of following these procedures on a per-batch basis. Document the rationale for what constitutes a "batch" or "lot" of product.
  - Establish and implement a written randomized sampling plan to a degree that would ensure a very low probability of an undetected contaminant.
  - Establish and implement a written procedure for analysis of raw materials for: (1) microorganisms of public health concern; (2) heavy metals; (3) chemical contaminants; (4) synthetic drugs; and (5) shelf-life testing.
  - Establish and implement a raw material receiving procedure to place incoming raw materials on an initial quarantine pending receipt of test results and confirmation that ingredient meets specifications. This procedure should include a rejection protocol for raw materials that do not meet specifications or whose analysis reveals the presence of microorganisms of public health concern, heavy metals, chemical contaminants, or synthetic drugs.
  - Establish and implement a written procedure for qualifying ingredient suppliers, including the procedures that trigger the disqualification of the supplier.

Recordkeeping

- Generally
  - All records should be kept for a minimum of 1 year past the shelf life date of the product, if shelf life dating is used, or 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records.
  - All records should be kept in a standardized manner so that they are readily accessible at the manufacturing facility for review by an independent third party auditor.
- Master Manufacturing Records[4]

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2 *See* 21 C.F.R. § 111.8 and 111.10.
3 *See* 21 C.F.R. § 111.15.
4 *See* 21 C.F.R. § 111.205 and 111.210.

- Establish and follow a written Master Manufacturing Record for each unique formulation of kratom product that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch.
- The Master Manufacturing Records must:
  - Identify specifications for the steps in the manufacturing process where control is necessary to ensure the quality of the kratom product, and that the kratom product is packaged and labeled as specified in the master manufacturing record; and
  - Establish controls and procedures to ensure that each batch of kratom product manufactured meets the specifications in the Master Manufacturing Record.
- The Master Manufacturing Records must include:
  - Name, strength, concentration, weight or measure of each ingredient used in each product for each batch size;
  - A statement of the theoretical yield of a manufactured kratom product expected at each step of the manufacturing process where control is needed to ensure the quality of the product, and the expected yield when manufacturing is completed, including the maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a batch is necessary and material review is conducted and disposition decision is made;
  - A description of packaging and a representative label, or a cross-reference to the physical location of the actual or representative label;
  - Written instructions, including:
    - Specifications for each step in the manufacturing process where control is necessary to ensure the quality of the kratom product and that the kratom product is packaged and labeled as specified in the master manufacturing record;
    - Procedures for sampling and a cross-reference to procedures for tests or examinations;
    - Specific actions necessary to perform and verify steps in the manufacturing process where control is necessary to ensure the quality of the kratom product and that the kratom product is packaged and labeled as specified in the master manufacturing record.

- Batch Production Records[5]
  - Establish and maintain batch production records each time you manufacture a batch of a kratom product.
  - Batch Production Records must:
    - Include complete information relating to the production and control of each batch; and
    - Accurately follow the appropriate Master Manufacturing Record, and each step in the Master Manufacturing Record must be followed for each batch of product.
  - The Batch Production Records must include:
    - The batch, lot, or control number of the finished batch of kratom product;

[5] *See* 21 C.F.R. § 111.255 and 111.260.

        - 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.