AMERICAN KRATOM ASSOCIATION

AKA Good Manufacturing Practice (GMP) Standards Program

These standards are effective on October 1, 2021, and are subject to periodic updates as new issues emerge that require additional safeguards for consumers. All participants are required to adhere to program updates as they are published. Manufacturers and distributors of kratom products should consult with their own legal counsel to assure compliance with FDA standards for the manufacturing, distribution, and marketing of kratom products, and to assure compliance with the AKA standards. The AKA cannot provide legal advice to program participants. Participation in the program does not take the place of federal and state requirements, and participation in the program does not guarantee that a manufacturer or vendor will not be subject to regulatory action by a federal or state agency.

PROGRAM BACKGROUND

The Food and Drug Administration (FDA) has reaffirmed its long-standing hostility towards kratom by using various regulatory schemes to further its efforts to interfere with consumer access to safe and legal kratom products when they are properly manufactured and marketed as a food product. No kratom product is safe from this interference given the aggressive FDA regulatory overreach, but there are important protective steps manufacturers and distributors can take to shrink the target the FDA has placed on kratom products. There are three foundational conditions that must be met to reduce the risk of unsafe kratom products being marketed to consumers:

1. Kratom manufacturers must use rigorous testing protocols to ensure quality kratom raw materials are used in the processing of kratom food products. FDA appropriately regulates the safety of kratom and using contaminated kratom raw materials, i.e., salmonella, E-coli, and heavy metals, poses a safety risk to consumers. Testing of raw materials is an essential step in the manufacturing and processing of safe and compliant kratom food products.
2. Kratom processing as a food or dietary supplement product must meet prevailing FDA good manufacturing practices (GMP). Manufacturers must comply with these standards, including acquiring the food processing equipment and adopting the recordkeeping and other requirements published by the FDA for food manufacturers.
3. All kratom products should meet or exceed labeling and marketing practice requirements to avoid any impermissible disease or drug claims that have not been subject to a new drug application (NDA) or as appropriate, a new dietary ingredient notification (NDIN) by the FDA, and that clearly provides basic information to a consumer on directions for use and contact information for the manufacturer.

Recent import alert enforcement actions by the FDA clearly show that FDA's policy is to classify all kratom products as either an unregistered new dietary ingredient (NDI) (Import Alert 54-15) or as an unapproved drug (Import Alert 66-41).

Import Alert 66-41 provides for detention without physical examination of unapproved new drugs where there is "evidence of marketing or promotion" of the product.[1] Assuming there are no implied or express disease or drug claims, marketing, or promotional materials accompanying the kratom at the time of entry, Import Alert 66-41 should not be applicable, but the FDA has determined the statutes authorizing import alerts provide the agency with broad discretion to protect public health.

Import Alert 54-15 applies to dietary supplements and bulk dietary ingredients that are kratom, and states "[k]ratom is a botanical that qualifies as a dietary ingredient….When marketed as a dietary ingredient, FDA also considers kratom to be a new dietary ingredient…."[2] FDA prohibits the importing of kratom because it considers the importation of kratom without an NDI notification an adulterated product as "there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury."[3] FDA requires a manufacturer and distributor of a dietary supplement to obtain an NDI if that dietary supplement contains a new dietary ingredient.[4] However, it is the position of the American Kratom Association (AKA) that FDA's policies have never and do not now place this burden on an importer that is not manufacturing and/or operating at the retail level.

Under 21 C.F.R. § 190.6, "before introducing or delivering for introduction into interstate commerce a dietary supplement that contains a new dietary ingredient…."[5] a manufacturer or distributor must file an NDI notification. Specifically, the Dietary Supplement Health and Education Act of 1994 ("DSHEA") "requires **the manufacturer or distributor** of an NDI, or of the dietary supplement that contains the NDI, to submit a premarket notification to FDA at least 75 days before introducing the product into interstate commerce or delivering it for introduction into interstate commerce."[6]

Kratom is not scheduled by the Drug Enforcement Administration ("DEA") as a controlled substance, nor is it considered to be a drug unless certain claims related to the cure, treatment, or prevention of disease are included in the labeling. FDA prohibits the importing of kratom because it considers the importation of kratom without an NDI notification to be an adulterated product given "there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury."[7] FDA requires a manufacturer and distributor of a dietary supplement to obtain an NDI if that dietary supplement contains a new dietary ingredient.[8]

FDA has the legal authority to take regulatory action against a manufacturer, distributor, or vendor of a food or dietary supplement product that is adulterated or misbranded under the standards set forth in the Food and Drug and Cosmetic Act ("FDCA").

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[1] Import Alert 66-41.
[2] Import Alert 54-15.
[3] *Id*.
[4] 21 C.F.R. § 190; *Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Draft Guidance for Industry*, August 2016, available at https://www.fda.gov/media/99538/download.
[5] 21 C.F.R. § 190.6 (emphasis added).
[6] *Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Draft Guidance for Industry*, August 2016, available at https://www.fda.gov/media/99538/download (emphasis added).
[7] *Id*.
[8] 21 C.F.R. § 190; *Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Draft Guidance for Industry*, August 2016, available at https://www.fda.gov/media/99538/download.

Under the FDCA, a product is adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to health, or the food is a dietary supplement or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling."[9] Additionally, FDA can deem a product adulterated if it requires a new dietary ingredient notification and pre-market review by FDA. Separately, a product is misbranded if its labeling bears any false or misleading information.

Since it would be unlawful for a manufacturer to market kratom as a drug, the open question is whether kratom should be marketed, and therefore regulated, as a food or dietary supplement. Under the FDCA a food is an "(1) article used for food or drink for man or other animals, (2) chewing gum, and (3) article used for components of any such article."[10] A "conventional food" is one that is consumed for taste, aroma, and nutritive value.[11]

FDA does not approve conventional food prior to marketing but does require manufacturers of food additives to submit a notification or conform to the terms of a regulation. FDA can and does deem food unsafe and adulterated when the Agency does not believe there is adequate safety data to support the conventional food. Food manufacturers are required to comply with FDA regulations such as Good Manufacturing Practices and labeling requirements.

AKA encourages all kratom be sold with the intended use as a food product to the extent possible. To do so, the kratom would first need to meet the definition of a conventional food.[12] Then, any labeling on the product that clearly shows the product is intended for use as a drug or as a dietary ingredient that has not been reviewed by the FDA in a new dietary ingredient notification (NDIN) is not in compliance with these AKA standards.

The AKA Good Manufacturing Practice (GMP) Standards Program is designed to ensure the safety and integrity of kratom food products that are marketed to consumers. The program establishes exacting manufacturing, testing, packaging, labeling, storage, distribution, marketing, and verification requirements for kratom food products that meet or exceed the minimum requirements for manufacturing food products established by the U.S. Food and Drug Administration (FDA). For example, companies participating in this program will need to perform several tasks including: test every production lot of kratom to ensure it is free of any microorganisms of public health concern, disclose ingredients in the product, and agree to independent 3rd party audits of their facility and compliance programs.

The AKA GMP Standards Program sets minimum standards for the methods, facilities, and controls used in the processing of kratom food products to provide consumers with confidence that the kratom product is safe for use and contains the ingredients and levels of alkaloids it claims to have.

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[9] This list is not an exhaustive list. 21 U.S.C. § 342; *Questions and Answers Regarding Mandatory Food Recalls*, FDA Guidance, November 2018, available at https://www.fda.gov/media/117429/download.

[10] 21 U.S.C. § 321(f).

[11] *See Distinguishing Liquid Dietary Supplements from Beverages Guidance*, January 2014, available at https://www.fda.gov/files/food/published/Guidance-for-Industry--Distinguishing-Liquid-Dietary-Supplements-from-Beverages-%28PDF%29.pdf.

[12] Products that don't meet that definition may need to be marketed as dietary supplements.

Vendors who qualify for this program will be listed as AKA Qualified Vendors. Kratom products that meet the standards of this program will be listed on the AKA website and will be eligible to bear the "AKA GMP Qualified" seal on their product labels. While the AKA does not endorse specific kratom products, the AKA does strongly encourage all consumers to buy only products from vendors who qualify for the AKA Qualified Vendor list.

Kratom can be in the form of raw leaf, powders, capsules, pills, tinctures, and extract products that otherwise comply with the standards of this program.

The AKA will, as needed, update the program requirements on the basis of scientific advances, and FDA communications, policy changes, and enforcement actions.

PROGRAM REQUIREMENTS

Application:

A kratom processor seeking to qualify for the AKA GMP Standards Program ("GMP Program") who manufactures or processes a kratom product as a food or herbal product is required to submit the application form and submit the prevailing annual registration fee, available at the following link:

[INSERT APPLICATION LINK AND FEE PAYMENT LINK]

Any manufacturer that manufactures, processes, or distributes a kratom product they manufacture in compliance with the GMP Program as a "co-packer" or "white label manufacturer" and seeks to attach the appropriate certifications to such products are required to submit an application and pay the prevailing annual registration fee for each separately labeled product. The forms and payment portal are available at the following link:

[INSERT APPLICATION LINK AND FEE PAYMENT LINK]

The AKA GMP Qualified designation does not allow the vendor to make any representations beyond that they have successfully passed an independent 3rd party audit that demonstrates they are compliant with the AKA GMP Standards Program. The AKA does not endorse the quality of the product, only that an auditor verifies that the following standards are being met. No GMP Program participant is permitted to make any claims that AKA endorses their product.

Facilities and Processes Audit:

Any company participating in GMP Program must submit to an independent 3rd party audit documenting compliance with the standards within this program, which are based, in part, on the FDA dietary supplement GMPs found at 21 CFR Parts 110 and111.[13] All auditors must be pre-approved by the AKA prior to audit through submission of the auditor's resume or CV; verifying the auditor is appropriately qualified to conduct the audit. Submission of auditor and qualifications must be sent to gmp@americankratom.org

[13] 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.

Auditor's minimum qualifications include:

- College degree in science related field, or equivalent experience;
- Minimum of 5-years work experience in a manufacturing, quality assurance, quality control and/or cGMP environment in either Pharmaceuticals, Biologics, Dietary Supplements or foods, with specific experience performing internal and/or external audits,
- America Society of Quality (ASQ), Quality Auditor Certification or equivalent experience;
- A written certification that no conflict of interest exists between the auditor and the applicant.

If applicants need a referral for a qualified auditor, please submit a request to gmp@americankratom.org. The AKA does not guarantee auditor results so applicants should carefully evaluate the qualifications and capabilities of auditors used to ensure compliance with this program.

Testing Facility:

All kratom testing required for compliance to the AKA GMP Program must be conducted by laboratories that are ISO/IEC 17025:2017 certified. Applicants are responsible for the selection of laboratories for testing that have the equipment and capabilities to appropriately test kratom products.

Use of the Term "Organic":

If a vendor chooses to use the term "organic" or any variation of the term on their labelling they should be compliant with all standards and requirements published by the National Organic Program (NOP), which is administered by the U.S. Department of Agriculture. For more information, visit this link: https://www.ams.usda.gov/rules-regulations/organic.

Nanotechnology:

Any vendor using nanotechnology to manufacture kratom must be compliant with FDA guidelines and standards governing the uses of the label description of nanotechnology. For more information, visit this link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considering-whether-fda-regulated-product-involves-application-nanotechnology.

Official AKA Seal:

Finally, upon acceptance of a satisfactory audit report, applicants who become AKA GMP Qualified will be authorized to use the official AKA GMP Qualified logo unless such authorization is revoked for non-compliance. No other logo, indicia, or graphic representation is authorized to depict participation in the program. The official AKA GMP Qualified logo can be used by Qualified vendors in good standing on packaging, website, and marketing materials. The vendor agrees to pay any administrative or legal costs associated with assuring compliance to this requirement when found to be in violation. Being AKA GMP Qualified does not in any way impact a manufacturer or distributor's obligations to comply with FDA and other regulatory requirements.

Truth in Labeling Program:

GMP Program participants must also be in full compliance with AKA's Truth in Labeling Program for kratom marketed as a food product. No structure function claims are permitted unless the kratom product has successfully registered their product with the FDA as a new dietary ingredient (NDI). No therapeutic or medical claims are permitted unless approved by the FDA in a new drug application (NDA). FDA regulations define marketing as any published materials that include claims for kratom products, including websites, social media platforms, blogs, banner advertisements, and any comments made by consumers making personal claims on any materials or platforms that are controlled by a vendor. For reference, vendors are advised to review the Federal Trade Commission (FTC) [14] and FDA[15] Advertising and Promotion Guidance and consult with an attorney qualified to evaluate food product labelling and packaging regulations. Any vendor found in violation of the AKA Truth In Labelling Program will be immediately disqualified from the AKA GMP Standards Program and will be required to apply for reinstatement when the vendor can demonstrate full compliance.

Audit Approval/Good Standing:

The AKA will review all audits of GMP Program participants and make the final determination on the qualification for the program. The AKA will have up to three business days from the submission of the annual audit to review the audit report. If additional information or inspection verification is requested by the AKA, the three-business day review period is restarted on the date a response is received with the requested information.

Qualified GMP Program participants agree AKA has the right to remove or suspend any "Qualified" participants from the program for any reason including, but not limited to, the following:

1. Failure to maintain the required standards of the GMP Program.
2. Failure to pay the annual registration fee.
3. Failure to submit an annual audit from an AKA approved auditor.
4. Failure to correct any audit findings identified in the audit report.
5. Multiple reports of adverse events associated with the participant's products associated with the marketed products.
6. Violations of the AKA Truth in Labelling Program.
7. Actions that negatively impact the good standing and reputation of the AKA.

Audits submitted to the AKA must reference the corresponding SOP number and title provided on the Audit Form. Auditors must use the prevailing AKA GMP Audit Form. Auditors should confirm they are using the prevailing application forms by requesting the form at gmp@americankratom.org.

GMP Program participants must adhere to the following standards:

Kratom product limitations. A processor shall not prepare, distribute, sell, or expose for sale any of the following:

[14] https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry
[15] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide

- A kratom product that is adulterated with a dangerous non-kratom substance. A kratom product is adulterated with a dangerous non-kratom substance if the kratom product is mixed or packed with a non-kratom substance and that substance affects the quality or strength of the kratom product to such a degree as to render the kratom product injurious to a consumer.
- A kratom product that is contaminated with a dangerous non-kratom substance. A kratom product is contaminated with a dangerous non-kratom substance if the kratom product contains a poisonous or otherwise deleterious non-kratom ingredient, including, but not limited to, the substances listed in Section 812 of the Controlled Substances Act (21 U.S.C. §801 et seq.)
- A kratom extract that contains levels of residual solvents higher than is allowed in USP 467.
- A kratom product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 2% of the overall alkaloid composition of the product.
- A kratom product containing any synthetic alkaloids including synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compounds of the kratom plant.
- A kratom product that does not provide adequate labeling directions necessary for safe and effective use by consumers, including a recommended serving size.

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.[16]
    - Establish and implement a personnel compliance training program. Maintain documentation of the training.
    - Provide introductory GMP training to all new personnel as well as annual GMP refresher 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.[17]
    - 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 products.
    - Establish and implement a written randomized sampling plan to a degree that would ensure a very low probability of an undetected contaminant.

[16] *See* 21 C.F.R. § 111.8 and 111.10.
[17] *See* 21 C.F.R. § 111.15.

- 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.
- Fully comply with FDA regulations on the sanitization of buildings, facilities, manufacturing, packing, or holding human food provisions to assure kratom products are not contaminated.[18]

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[19]

  - 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

[18] See 21 C.F.R. § 110.20, 110.35, and 110.37.
[19] *See* 21 C.F.R. § 111.205 and 111.210.

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.
        - A validation procedure to assure the sanitation methods are effective for the purpose which they are required that include sanitation records, procedure adherence records, and validation method records.

- Batch Production Records[20]

    - 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;
        - 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;

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

        - 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 annual 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, medical, therapeutic, or unauthorized health claims (ex. claims regarding the treatment, cure, prevention, or mitigation of ailments or diseases).

- The labels or marketing of kratom products shall not infer in any way the product will produce a “high” to a consumer.
- The labels, labeling, or advertising of any kratom product be fully compliant with prevailing FDA standards for 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 and a “use by” date.
- Each finished product should be labeled, at a minimum, with an affirmative statement that the proportional allocation of the mitragynine and 7-OH alkaloids present in the natural plant has not been altered.
- Each finished product label must advise consumers to consult with a physician for an appropriate amount of kratom per serving.
- No kratom products may be sold to individuals under the age of 18 (or 21 if that is the law in a specific jurisdiction in which the kratom product is marketed).
- The label should bear a statement that pregnant women should consult a physician before use.
- 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.”
- All vendors much comply with local and state labeling and advertising requirements (ex. California’s Proposition 65).
- Vendors should avoid language such as dietary supplement, dietary ingredient, supplement facts, etc. Consult a legal professional for additional information.

State Regulations

Vendors must be compliant with any prevailing state regulatory rules promulgated by the Kratom Consumer Protection Act (KCPA) in the any state where kratom products are marketed. Participants should also avoid marketing kratom products in states or localities where the sale of kratom is prohibited. As new rules are published pursuant to passage in any state, those rules are also incorporated by reference in the standards for participation in this program. Please note, while not a requirement of this program, state OSHA requirements are applicable to all vendors who are manufacturing and/or packaging onsite. For more information, visit the applicable state OSHA website.

Compliance

All GMP Program participants are required to adopt these standards and to maintain compliance with the standards while participating. Where there is a more stringent requirement between the GMP Program and the published state rules, the more restrictive provision is required of all participants. A participant that adopts this code is required to submit to the AKA a certification that the Company has adopted the code and has implemented an effective compliance program.

The AKA will publish on its website a list of those Companies who have qualified for the GMP Program and have had their certification verified by an independent third-party auditor.

Any participating vendor that is found to be in non-compliance or refuses to provide an independent certification of compliance when requested will be suspended from the program. Reinstatement to the program requires a refiling of the application forms, payment of the annual fee, and an independent third-party audit documenting compliance as of the date of the refiled application.

The AKA reserves the right to report any violations of these standards that put consumers at risk to contaminated or adulterated products to the FDA. Such violations include deliberate actions, flagrant disregard for the critical elements of the GMP standards program, or for violations of these standards that impair the good standing and reputation of the AKA GMP Standards Program.

To register, click on the following link: https://aka.salsalabs.org/2021akagmpstandardsregistrationfee

For any questions on this program, please submit your requests in writing to gmp@americankratom.org