AKA GOOD MANUFACTURING PRACTICE (GMP) STANDARDS PROGRAM 4.0

These standards are effective on January 1, 2025, and are subject to periodic updates as new issues emerge that require additional safeguards for consumers. The GMP 4.0 program supersedes the requirements for past GMP programs. Participants are required to comply with these program requirements following the renewal date of participation in the program.

All participants are required to adhere to GMP 4.0 program updates as they are published. Those who manufacture, package, label, holding, or distribute of kratom-containing products should consult with their own legal counsel to assure compliance with all applicable federal, state and local jurisdiction regulations of kratom-containing products, and to assure compliance with the AKA GMP Standards Program.

The AKA cannot provide legal advice to program participants. Participation in the program does not take the place of federal, state, and local jurisdiction requirements, and participation in the program does not guarantee that a vendor will not be subject to regulatory action by a federal, state, or local regulatory agency.

The AKA GMP Standards Program does not certify the safety of any kratom product – that is a responsibility of the manufacturer. The GMP Standards Program is focused on the manufacturing processes and minimum labeling requirements for products marketed to consumers.

PROGRAM OBJECTIVES

The goal of AKA's GMP Standards Program is to provide consumers with information on kratom manufacturers who voluntarily agree to adhere to good manufacturing processes (GMPs) in the manufacturing of kratom-containing products. Each vendor must produce a certified compliance audit report from an independent auditor. To accomplish this, Program participants that qualify and maintain the Program's high standards will be listed as an AKA GMP Qualified Vendor. The listing of a vendor as an AKA Qualified Vendor is not an endorsement by the AKA of the product(s) marketed by that manufacturer, only that the facility adhered to GMP requirements.

Any products regulated by the FDA must satisfy distinct, minimum statutory and regulatory obligations relative to how the product is manufactured, packaged, labeled, and held. There are likely also similar obligations that must be satisfied pursuant to statutory and regulatory requirements of state and local jurisdictions. AKA's GMP 4.0 Standards Program is not intended to replace such statutory and regulatory requirements. Program participants are responsible for ensuring their practices satisfy all applicable statutory and regulatory requirements.

The manufacturer has the obligation to meet federal requirements to have a reasonable basis for the safety of products introduced to the market under the conditions of use (labeling).

The AKA Good Manufacturing Practice (GMP) Standards Program 4.0 is designed to ensure that kratom-containing products are manufactured under verified quality standards, but it is important to emphasize that GMP certification from the AKA is not an endorsement of a manufacturer or any specific finished product. Manufacturers cannot interpret participation in or certification through the AKA GMP Standards Program as an approval or endorsement of the safety or quality of the kratom products themselves, nor should it be portrayed as an endorsement of the manufacturer.

The purpose of the program is solely to verify that the facility where the product was manufactured adheres to GMP standards. This certification does not extend to endorsing or validating the safety or benefits of any finished product manufactured in a GMP-compliant facility.

Manufacturers and vendors are responsible for ensuring that the final product meets all regulatory requirements, including safety testing and labeling, and they must have a reasonable basis for marketing their products under specific labeling (conditions of use). The AKA GMP Standards Program only verifies that the manufacturing processes are compliant with industry standards and does not evaluate the finished product itself. As such, participants should not imply or suggest that the AKA has endorsed or approved any specific product. The AKA's role in this program is strictly to confirm that good manufacturing practices have been followed, not to validate individual products.

This distinction is crucial for ensuring transparency and maintaining consumer trust, as the GMP certification signifies compliance with manufacturing standards, not an endorsement of the product's safety or effectiveness.

The AKA Good Manufacturing Practice (GMP) Standards Program 4.0 recognizes that facilities already inspected and approved as an FDA-registered Food Facility can properly maintain they are compliant with the AKA GMP 4.0 Program. Manufacturers are still required to meet program requirements to make any representation they participate in the GMP 4.0 program. Facilities that have undergone an FDA inspection and maintain their FDA Food Facility registration can certify their FDA approval as evidence of compliance with the applicable federal manufacturing standards. While participation in the AKA GMP 4.0 Standards Program still requires adherence to AKA-specific standards, FDA-approved facilities may use their FDA Food Facility registration and compliance status as an alternative form of initial certification to satisfy program requirements.

However, these facilities will still be subject to all other aspects of the AKA GMP 4.0 Standards Program, including, but not limited to, periodic audits, product testing requirements, and labeling compliance reviews. This provision ensures that facilities

maintaining FDA registration can enter the AKA GMP 4.0 Program while maintaining transparency and adherence to industry standards.

It is essential to note that even in the case of an FDA-registered facility, GMP certification from the AKA remains a recognition of the facility's compliance with good manufacturing processes. It does not constitute an endorsement or approval of any specific finished product produced in the facility.

REGULATORY BACKGROUND

Kratom, as a botanical, satisfies the definition of a dietary ingredient at section 201(ff) of the Federal Food, Drug, and Cosmetic Act (the Act). FDA has determined that kratom is a new dietary ingredient under section 413 of the Act. The Act requires the manufacturer or distributor of a dietary supplement submit a New Dietary Ingredient Notification (NDIN) if that dietary supplement contains a new dietary ingredient that has not been present in the food supply and "used as food" in a form that has not been chemically altered. There have been several NDINs submitted to FDA for kratom and kratom-derived products. It is also possible that kratom has been present in the food supply.

It is the responsibility of Program participants to have a basis for legally marketing their kratom-derived products. The FDA has never banned kratom and cannot determine that any specific kratom-derived product is adulterated without first performing a specific evaluation of that product. As with other food products, however, such as those containing cannabidiol (CBD), the FDA has taken targeted enforcement action against specific kratom manufacturers if they have been found to market kratom as an unapproved drug. Specifically, the FDA has issued Warning Letters to a number of kratom companies for making unproven medical claims, including opioid treatment claims.

The U.S. Food and Drug Administration (FDA) has imposed Import Alerts all kratom raw materials being imported into the U.S. and those Import Alerts remain in effect today - one regarding unapproved new drugs (Import Alert 66-41) and one regarding dietary supplements (Import Alert 54-15).

- 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 where associated therapeutic claims are made. Assuming there are no marketing or promotional materials accompanying the kratom at the time of entry, Import Alert 66-41 would seem to be inapplicable.

- 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, the FDA also considers kratom to be a new dietary ingredient...." It 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.” The Act requires the manufacturer or distributor of a dietary supplement obtain an NDI if that dietary supplement contains a new dietary ingredient that has not been present in the food supply and “used as food” in a form that has not been chemically altered.

In 2024, Kratom sales remain legal and largely unregulated. There are states that have enacted legislation commonly referred to as the Kratom Consumer Protection Act (KCPA). In these states, the KCPA provides consumer protection regulations on kratom vendors that require compliance with good manufacturing practices, no adulteration or use of synthesized kratom alkaloids, proper labeling, and age restrictions to protect the sale of unsafe or adulterated kratom products.

At the federal level, the Federal Kratom Consumer Protection Act currently proposes the following regulatory framework for kratom in the US:

- Protects kratom from FDA overregulation and creation of de-facto regulatory bans using import alerts or FDA enforcement actions on restricting manufacturing or sales of kratom products based on the FDA’s own classification of kratom as an adulterated food, dietary supplement, dietary ingredient, or as a new dietary ingredient requiring notification. These decisions will have to be based on scientific evidence and data, not the FDA’s bias against kratom.

- Establishes an inter-agency Kratom Research Task Force to coordinate and report to the Congress on a quarterly basis on all research on kratom being funded by the federal government. The Task Force will hold public meetings with experts to increase public awareness of kratom research and will require the FDA to publish records of this research on the FDA website.

- Enacts requirements for full transparency for all government-funded research on kratom that addresses current evidence and data on consumer safety and addiction issues and creates an open platform for the public to comment on the use of kratom and its effects.

PROGRAM REQUIREMENTS

With input from industry representatives, AKA’s GMP 4.0 Standards Program has been reframed to better suit the current practices and activities required to manufacture and bring a kratom-containing product to market. To this end, the GMP 4.0 Standards Program includes requirements that participants must satisfy to demonstrate that they have taken steps necessary to ensure that products are manufactured, packaged, labeled, and stored in a way that meets high quality standards the FDA has set concerning Current Good Manufacturing Practices and that the label and labeling of such products is done in a

manner that ensures consumers have all the meaningful information required to make an informed purchasing decision.

The scope of the Program's GMP 4.0 requirements are based off 21 C.F.R. Part 111 – "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements." It is not necessary for participant's products to be dietary supplements. The process of bringing a kratom-containing product to market can be fractured with many different parties performing any of the required tasks. Participants in the program are only required to satisfy those program requirements that apply to the specific activities for which they are responsible for performing in the process of bringing their kratom-containing products to market.

Program participants should note that requirements for final product testing include that all final products be tested, prior to release, to confirm that they are not contaminated with pesticides, heavy metals, or microbes that would cause the product to be adulterated.

The scope of the Program's Label and Labeling requirements are largely based on AKA's model Kratom Consumer Protection Act. In addition to meeting program standards, participants must ensure that the label, labeling and advertising of their products be fully compliant with all applicable statutory and regulatory requirement, such as those enforced by the Federal Trade Commission and the FDA. The label and labeling requirements for AKA's GMP Standards Program 4.0 can be found here.

AKA's GMP 4.0 Standards Program certification process is envisioned as a collaborative one, intended to support and facilitate participants achieving certification and better complying with the requirements established by AKA. The program is intended to utilize a phased approach to participating manufacturers achieving certification, providing the applicant with constructive feedback whenever possible.
The certification process includes the following requirements:

1. Application, submit registration fee (Annual fee for all participants)
2. Orientation call, pre-audit preparation by participant;
3. Auditor initial questionnaire and request for documents;
4. Auditor review of responsive material, provides any feedback and if necessary, suggests corrective action;
5. On site audit by 3rd party auditor;
6. Auditor review of observations, gap analysis, feedback, corrective actions, "score";
7. Review of audit results by AKA;
8. Certification;