

AKA Good Manufacturing Practice (GMP) Standards Program -3.0

These standards are effective on April 1, 2023, 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. 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.

PROGRAM BACKGROUND

The ultimate goal of AKA's GMP Standards Program is to provide consumers with information to help them make an informed decision regarding their selection of kratom-containing products. To accomplish this, Program participants that qualify and maintain the Program's high standards will be listed as an AKA Qualified Vendor and the products they manufacture or distribute under the standards of the program can be listed on the AKA website as a "Qualified Vendor" and will be eligible to bear the "AKA GMP Qualified" seal on its products, the label and labeling of which was evaluated during the program evaluation process. The listing of a vendor as an AKA Qualified Vendor and displaying the AKA GMP Qualified seal on their qualifying products is intended to convey to consumers the quality of the products they are considering purchasing.

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 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 GMP Standards Program includes requirements that participants must satisfy to demonstrate that they have taken steps necessary to ensure the safety, identity, wholesomeness, and quality of the kratom-containing products they manufacture or distribute and that the label and labeling of such products ensures consumers have all the meaningful information required to make an informed purchasing decision.

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 2023, 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 Protecting Consumer Access to Kratom from Government Overreach 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 Standards Program – 3.0, has been reframed to better suit the current practices and activities required to bring a kratom-containing product to market. To this end, the GMP Standards Program includes requirements that participants must satisfy to demonstrate that they have taken steps necessary to ensure the safety, identity, wholesomeness and quality of the kratom-containing products they manufacture 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 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 perform 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 GMP requirements for AKA's GMP Standards Program 3.0 can be found [here](https://www.amerikankratom.org/gmp-standards-program) (Also via <https://www.amerikankratom.org/gmp-standards-program>)

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 3.0 can be found here: [link to pdf of label and labeling standards].

AKA's GMP Standards Program 3.0 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 is:

1. Application, submit registration fee;
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. Up to three (3) site audits;
8. Review of audit results by AKA;
9. Certification;
10. Annual requirements, periodic re-audits by 3rd party auditor, annual fee.