AKA cGMP Compliance Audit

GENERAL

Submission Information

Date(s) of audit: 08/08/2025 **Purpose of audit:** New Audit Renewal Audit ☑	**Location of audit:** **Bulk Kratom Now** [redacted]

Company Point of Contact

Name/Title: [redacted]	**Telephone:** [redacted]
	Email: [redacted]

Summary of Audit Results

Bulk Kratom Now has successfully passed their AKA cGMP recertification audit. All lab testing is done through a third party lab - which tests for microbiologics, alkaloid profiles and heavy metals. All production and processing of the kratom is done at a GMP accredited supplier. Only customer service and fulfillment is handled by Bulk Kratom Now. All documentation is in place and is readily available for employee use and auditing purposes.

Compliance: 4
Compliance Suggestion: 1
Minor Non-Conformance: 0
Major Non-Conformance: 0

PERSONNEL/MANUFACTURING

Personnel

	Compliance	Compliance Suggestion	Minor Non-Conformance	Major Non-Conformance
The following standards have been implemented to: (a) Establish and follow written procedures to prevent microbial contamination from sick or infected personnel and for hygienic practices at the facility (b) Establish and implement a personnel compliance training program (c) Maintain documentation of training	X			

Findings:
Cleaning logs are in place for the facility. Log specifies date, what was cleaned and employee initials for who completed the task. All surfaces were stainless steel and cleaned on a regular basis to prevent microbial contamination. All storage bins are cleaned out on a regular basis and wiped down. Facility was in a clean manner at the time of the audit. Warehouse and all surfaces were clean and organized. Policy in place for sick personnel to not handle kratom products.

Additional Notes:

RECORD KEEPING

General

	Compliance	Compliance Suggestion	Minor Non-Conformance	Major Non-Conformance
The following standards have been implemented to: (a) 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 (b) 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.		X		

Findings:
All records are readily available for auditing via company computer and at third party facility. Procedures state that all records should be kept for a minimum of 2 years - including items and records of items in long term storage.

Additional Notes: Retain a sample of finished product in addition to the raw product from co-packer

ADVERSE EVENT REPORTING SYSTEM AND RECALLS

Written Adverse Event Reporting System

	Compliance	Compliance Suggestion	Minor Non-Conformance	Major Non-Conformance
The following standards have been implemented to: (a) 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. (b) 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. (c) Monitor consumers who experience an adverse health	X			

event related to a kratom product. (d) Monitor potential contamination or adulteration of kratom products. (e) Monitor vendors selling counterfeit, contaminated, or adulterated kratom products. (f) Monitor manufacturers or distributors of kratom products using health claims.				

Findings:
All product complaints are tracked via company email. Per Product Recall and Customer Complaints Procedure - product recalls are broken up into different classifications depending on the severity of the recall. There is a form and letter used in the event of product recalls. Company has chosen to implement third party co-packer (TPS) Product Recall Procedure. The procedure has been found to be sufficient. No recalls have been issued/found necessary since last audit.

Additional Notes:

Recalls

The following standards have been implemented to:	Compliance	Compliance Suggestion	Minor Non-Conformance	Major Non-Conformance
(a) Establish and implement a written recall procedure.	X			

Findings:
There is a product recall procedure in place that specifies the necessary steps for recalling a product in the event that product complaints meets or exceeds the threshold set forth in the Product Recall Procedure. No recalls have been issued/found necessary since last audit.

Additional Notes:

MARKETING PRACTICES

Labeling and Advertising

The following standards have been implemented to:	Compliance	Compliance Suggestion	Minor Non-Conformance	Major Non-Conformance
(a) 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. (b) The labels, labeling or advertising of any kratom product should not bear any structure/function claims. (c) The labels, labeling or advertising of any kratom product must not reference any research or clinical data. (d) Each finished product label must include a batch or lot number.	X			

(e) Each finished product must be labeled to disclose the mitragynine and 7-OH alkaloid content of the product. (f) Each finished product must advise consumers to consult a physician before using product. (g) All labels, labeling or advertisitng must clearly state that no kratom products may be sold to individuals under the age of 18 or applicable local law (h) The label must bear a statement that pregnant women should not use kratom products during pregnancy. (i) All labels, labeling, or advertising must include the following statement: “This product is not intended to diagnose, treat, cure, or prevent any disease or condition."				

Findings:

Confirmed that all finished product meets labeling specifications set forth by the AKA GMP program. All product is labeled with mitragynine and 7OH levels, FDA disclaimer statement, necessary age disclaimers, lot number and exp date. All labels and marketing material does not contain any medical claims and/or structure/function claims

ATTESTATION

I hereby certify that all information contained in, or referenced by, this report is true, accurate and complete. No information is false or misleading; no omissions have knowingly been made that may affect its accuracy and completeness.

I hereby confirm that the company/facility referenced in Section B of this report has implemented and is following the AKA GMP Standards as outlined in the document found at http://www.americankratom.org/images/file/GMP-Standards-for-Kratom-Products.pdf

Name(s) of Auditors (Please Print):	Signature of Auditor(s):	Date:
Kyndra Price		08/08/2025