AKA cGMP Compliance Audit

GENERAL

Submission Information

Date(s) of audit: 07/28/2023 **Purpose of audit:** New Audit Renewal Audit ☑	**Location of audit:** **New Dawn Kratom** [redacted]

Company Information

Company Name: New Dawn Kratom

Address: [redacted]

City: Cypress	**State: CA**	**Postal Code:** [redacted]
Telephone: (855) 813-2105	**Website: NewDawnKratom.com**	
Years in business: 2	**Number of employees: 3**	

Products/Services offered: Kratom e-commerce

Company Point of Contact

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

Auditee Information

Location of Controlled Master Documents: **Company computer for master documents and records**	**Name(s) of personnel:** [redacted] **- CEO** [redacted] **- COO** [redacted] **- Customer Service** [redacted] **- Fulfillment Specialist** [redacted] **- Fulfillment Specialist**

Summary of Audit Results

After completion of the AKA cGMP recertification audit - it is my recommendation that New Dawn Kratom is in compliance with the AKA cGMP program and has successfully passed their audit. All lab testing is done through a third party lab - which tests for microbiologics, alkaloid profiles and heavy metals. All documentation is in place and is readily available for employee use and auditing purposes. Fulfillment is now handled through a third party company that is GMP certified.

Compliance: 9
Compliance Suggestion: 0
Minor Non-Conformance: 0

Major Non-Conformance: 0

PERSONNEL/MANUFACTURING

Personnel

The following standards have been implemented to:	Compliance	Compliance Suggestion	Minor Non-Conformance	Major Non-Conformance
(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			

Documents Audited:
GMF002 Rev A - Employee Training Record
GML004 Rev A - Cleaning Log

Findings:
Employees have been trained and recorded via GMF002 Rev A. 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. Fulfillment is now being completed at new facility. Warehouse and all surfaces were clean and organized.

Additional Notes:

Manufacturing Facility and Equipment

The following standards have been implemented to:	Compliance	Compliance Suggestion	Minor Non-Conformance	Major Non-Conformance
(a) Establish and implement procedures to ensure facility is in a condition that protects against the contamination of ingredients, finished products and contact surfaces (b) Clean and sanitize storage, production, processing and packaging areas according to an established schedule (c) Verify the effectiveness of cleaning and sanitation operations by conducting swabbing of contact surfaces according to an established schedule and sampling plan	X			

Documents Audited:
GML004 Rev A - Cleaning Log
GMP006 Rev A - Cleaning
GMP003 Rev A - Testing

Findings:
Company has moved their fulfillment to a new third party, GMP certified, company. All surfaces and storage bins were clean and organized. Facility is well kept. Company continues to use stainless steel surfaces for production purposes and shipping/handling purposes. All storage bins are easily wiped down and cleaned/stored in a proper manner. Bins are organized by company name, product, and size.

Additional Notes:

Manufacturing Operations

The following standards have been implemented to:	Compliance	Compliance Suggestion	Minor Non-Conformance	Major Non-Conformance
(a) Establish and implement written procedures for 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 rationale for what constitutes a “batch” or “lot” of product.	X			
(a.1) 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 heath concern, heavy metals, chemical contaminants, or synthetic drugs				
(b) Establish and implement a written randomized sampling plan to a degree that would ensure a very low probability of an undetected contaminant.				
(c) 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				
(d) Establish and implement a written procedure for qualifying ingredient suppliers, including the procedures that trigger the				

Documents Audited:
GMP001 Rev A - Receiving
GMP002 Rev A - Quranatine
GMP004 Rev A - Packaging
GMP005 Rev A - Fulfillment
GMP003 Rev A - Testing
GMF003 Rev A - Approved Supplier List
Receiving/Testing/Production/Long Term Storage Log

Findings:
Product audited was found to have proper traceability and records from start to finish. All proper identification on production bins and boxes was in place. Lots are assigned at time of receipt and have a unique identifier to note whether the kratom is green, white or red. Product is sampled at random for testing

to ensure an accurate randomized test is perfomred on each batch. Test log shows product that was sent out for test and shows test results for product that was deemed as approved. Testing log is color coded for easily identifying what lot numbers are no longer in use, and what lot numbers are currently being used for fulfillment. Only product in quarantine is that in bulk located in Las Vegas warehouse and is not used for production fulfillment at new facility. Approved supplier list is readily available and is used for placing purchase orders.

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			

Documents Audited:
Lot # NDK2056Y - Yellow 350 caps
Lot # NDK2055X - Red 500g
Lot # NDK2056Y - White 250g

Findings:
All records are readily available for auditing via company computer. 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:

Master Manufacturing Records

	Compliance	Compliance Suggestion	Minor Non-Conformance	Major Non-Conformance
The following standards have been implemented to: (a) 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 (b) 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. - Established controls and procedures to ensure that each batch of kratom product manufactured meets the specifications in the Master Manufacturing Record. (c) 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: ii. 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 iii. Procedures for sampling and a cross-reference to procedures for tests or examinations iiii. 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	X			

Documents Audited:
GMP008 Rev A - Weight Scale Calibration
GMP003 Rev A - Testing
Receiving/Testing/Production/Long Term Storage Log

Findings:
Production will eventually be handed off to third-party co packaging facility once current inventory is depleted. Control is in place at time of receipt and releasing product from quarantine (including reviewing test results and deeming product as acceptable or rejected). Product being approved from testing to be used in production is still done by Gabe Swope. Product is color coded on company log to note what lot numbers are available, not for use, closed out and waiting for testing. Labels generated by management for production to use per specific lot number and size of packaging.

Additional Notes:

Batch Production Records

	Compliance	Compliance Suggestion	Minor Non-Conformance	Major Non-Conformance
The following standards have been implemented to: (a) Establish and maintain batch production records each time you manufacture a batch of a kratom product - per predetermined batch size. (reference Manufacturing Operations part A) (b) 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. (c) 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; -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	X			

Documents Audited:

Receiving/Testing/Production/Long Term Storage Log

Kratom Lot Tracing Log

Findings:
All storage containers are properly identified with lot number, mitragynine content and 7OH. Kratom Lot Tracing Log shows each individual lot number with the start of use and the end of use dates. Lots highlighted in green are still in use. Product is still recieved and batched in groups of 1,000 kilos for traceability and processing. Product is no longer color coded with bins and shelf labeling. Product is stored per company name, strain and bag size.

Additional Notes:

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 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.	X			

Documents Audited:

GMP007 Rev A - Product Recall - Customer Complaints
GMF001 Rev A - Adverse Effects Questionnaire

Findings:
All product complaints are tracked via different folders set up within company email. Product complaints are tracked via Shipping Complaints, Adverse Effects and Product Complaints. Per Product Recall and Customer Complaints Procedure - thresholds have been put in place for escalation to management for customer complaints. Tracking sperad sheet for batch and lot tracking is used, if necessary, to help trace product through any customer complaints. Verified that company still uses same customer service protocols and tracking of customer complaints. No recalls have been issued/found necessary since last audit.

Additional Notes:

Recalls

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

Documents Audited:
GMP007 Rev A - Product Recall - Customer Complaints

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

	Compliance	Compliance Suggestion	Minor Non-Conformance	Major Non-Conformance
The following standards have been implemented to: (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. (e) Each finished product must be labeled to disclose the mitragynine and 7-OH alkaloid content of the product.	X			

(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."				

Documents Audited:
GMP004 Rev A - Packaging
Lot # NDK2056Y - Yellow 350 caps
Lot # NDK2055X - Red 500g
Lot # NDK2056Y - White 250g

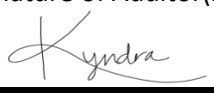
Findings:
Confirmed that all finished product meets labeling specifications set forth by the AKA GMP program. All product is labeled with mitragynine and 7OH levels, FDA disclaimer statement, necessary age disclaimers, lot number and exp date. All labels and marketing material does not contain any medical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

Additional Notes:

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		07/28/2023