

EXHIBIT 15

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

KATHLEEN MOLLER	*	CIVIL ACTION NO. 24-0228-WBV-DPC
	*	
VERSUS	*	JUDGE WENDY B. VITTER
	*	
MARTIAN SALES, INC; JOPEN, LLC,	*	MAGISTRATE DONNA PHILLIPS
a Texas limited liability company;	*	CURRAULT
JOHNSON FOODS, LLC, a Wyoming	*	
limited liability company; LP IND., LLC,	*	
a Wyoming limited liability company;	*	
CAG HOLDINGS, LLC, a Wyoming	*	
limited liability company; RMH	*	
HOLDINGS, INC., a Wyoming	*	
corporation; ABC INSURANCE	*	
COMPANY and John Does 1-4.	*	
	*	
	*	
*****	*	

DECLARATION OF EVELYN CADMAN

I, Evelyn Cadman, am over the age of eighteen (18), competent to testify, and make this Declaration:

1. I am an expert witness for Plaintiff in the above-captioned case.
2. On October 24, 2025, I submitted a Freedom of Information Act (FOIA) request to the Food and Drug Administration (FDA) regarding inspection of Defendant JOPEN, LLC and the July 26, 2024, warning issued by FDA related to a report of death associated with OPMS Black Liquid Kratom. See, *FDA Warns Consumers Not to Use Optimized Plant Mediated Solutions (OPMS) Black Liquid Kratom*, <https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-not-use-optimized-plant-mediated-solutions-opms-black-liquid-kratom> (last accessed Feb. 26, 2026).

3. On February 19, 2026, I received FDA'S partial response to the FOIA request.
4. A true and correct copy of FDA's partial response is attached hereto as Exhibits A1-A6.
5. As stated at page 14 of Exhibit A-2 under "General Discussion with Management," David Gabbay, owner and operator of JOPEN, LLC, and the FDA investigator had a discussion "regarding the violative/adulterated products due to kratom." Mr. Gabbay was directly informed "that the FDA does not recognize kratom as an ingredient to be used in food items."

I declare under penalty of perjury that the foregoing is true and correct.

Executed On: February 26, 2026

Electronically Signed 2026-02-26 16:20:13 UTC - 48.110.104.157
Evelyn Cadman
Nintex AssureSign® c0cecf3a-6ed7-47e1-b668-b38012cc51a

Evelyn Cadman

EXHIBIT A-1



02/19/2026

FDA FOIA Request Number: FDA-FOIA-2025-12305-OIIB2-1

Released Deliverable: FDA-FOIA-2025-12305-OIIB2-1 (02/19/2026 04:29:50 PM) Evelyn Cadman (FDA Compliance Simplified), Commercial Use

Evelyn Cadman
FDA Compliance Simplified
9172 West 92nd Avenue
Westminster, CO United States 80021
ecadman@fdasimplified.com

Dear Requester:

The attached record(s) are being provided by the U.S. Food & Drug Administration's FDA/OC/OO/OMES/ODIGA/DID/FIB/OIIB2, in response to your Freedom of Information Act (FOIA) request, referenced above, for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act regarding:

I request that a copy of documents containing information regarding the FDA's investigation and findings regarding adverse event reports arising from OPMS and Whole Herb branded products. This would include documents arising from the May 2024 report of an OPMS related death, which led to the FDA's August 29, 2024 inspection (Inspection ID 1247811) of Jopen LLC, d.b.a A1 Wholesale, FEIN 3011941572, located at 4949 Beeman St., Dallas, TX 75223. The documents requested include, but are not limited to:

- a. Records of the FDA attempts to communicate with persons responsible for the products, including calls and emails by the FDA Consumer Complaint Coordinator and the Office of Chief Counsel to the available contact information, such as 213 221 8049 and info@OPMSKratom.com**
- b. Establishment Inspection Reports (EIR) related to inspection 1247811 of Jopen LLC, d.b.a A1 Wholesale, FEIN 3011941572 on August 29, 2024**
- c. Any Form 484s and related Sample Collection information related to the inspection**
- d. Copies of any documents collected from the facility as part of Inspection 1247811 of Jopen LLC, d.b.a A1 Wholesale, FEIN3011941572**
- e. Copies of any correspondence related to Inspection 1247811 of Jopen LLC, d.b.a A1 Wholesale, FEIN3011941572, including but not limited to investigation memos, 483s and responses, determination letters and response, consent decrees and related correspondence, any FDA requested recall letters and related correspondence, FMD-145 letter, any Warning Letter or Untitled Letter and responses or related correspondence.**
- f. Copies of any correspondence or documents regarding persons associated with the manufacture and distribution of OPMS and Whole Herbs kratom products, including: Jopen LLC, d.b.a A1 Wholesale, FEIN3011941572; Martian Sales, Inc.; Nuza (fka Advanced Nutrition); David Gabbay; Itamar David; Peyton Palaio; Mark Reilly; Mark Jennings; Gwendolyn Payton; Benjamin England; John K. Pratt; Mac Haddow; and Robert Durkin**

Your request is granted in part. We are enclosing 79 pages with this response. After a thorough review of the responsive records, we have determined that portions of the information are exempt from disclosure under FOIA exemptions of the FOIA 5 U.S.C. § 552, as checked, amended, and delineated below:

U.S. Food & Drug Administrator
10903 New Hampshire Avenue
Silver Spring, MD 20903

www.fda.gov

Exemption (b)(3) permits the withholding of information specifically exempted from disclosure by statute. Under this exemption we are invoking .

Exemption (b)(4) permits the withholding of trade secrets, and commercial or financial information obtained from a person that is privileged or confidential. We have determined that portions of the enclosed records satisfy these criteria.

Exemption (b)(6) permits the withholding of information which, if released, would constitute a clearly unwarranted invasion of personal privacy. In this case, it was determined that there is no countervailing public interest qualifying under the standard set forth, under exemption (b)(6), to release the personal identifying information of certain third parties.

Exemption (b)(7)(C) protects from disclosure records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information could reasonably be expected to constitute an unwarranted invasion of personal privacy.

In determining to withhold such information, FDA considered 5 USC 552(a)(8)(i), when applicable, and whether FDA reasonably foresees that disclosure of such information would harm an interest protected by the relevant exemption(s) and whether disclosure is prohibited by law.

In accordance with 45 CFR § 5.61 and 21 CFR § 20.41(b)(5), you have the right to appeal this determination. Your appeal should clearly identify the agency determination that is being appealed. It would be helpful if you provide specific reasons explaining why you believe the agency's adverse determination should be reconsidered. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed or emailed within 90 days from the date of this response, to:

Director, Office of Management and Enterprise Services
U.S. Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
FDAFOIA@fda.hhs.gov.

Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal." Items arriving or delivered after 5 p.m. Eastern Time will be deemed received on the next workday.

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Ms. Charis Wilson at 240-402-9116. You may also contact the FDA FOIA Public Liaison for assistance at: Office of Management and Enterprise Services, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, email: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, MD 20740-6001; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769; email at ogis@nara.gov.

The following charges for this request to date may be included in a monthly invoice. Please do not submit payment unless you receive an invoice.

SEARCH: 1.0(58.00) = \$58.00 REVIEW: 6.0(58.00) = \$348.00 Total Estimated Fees: \$406.00

U.S. Food & Drug Administrator
10903 New Hampshire Avenue
Silver Spring, MD 20903

www.fda.gov

This is the DID/FOIA/Branch 2 final response to your FOIA request. If you have any questions about this response, you may contact me at JANICE.STRAIGHT@FDA.HHS.GOV or telephone 240-402-8314. **Please note, your request is assigned to additional office(s) within FDA. A separate response will be sent by the additional FDA office(s).**

Sincerely,

JANICE L. Digitally signed
by JANICE L.
STRAIGHT -S
Date: 2026.02.19
13:41:41 -07'00'
STRAIGHT
-S

Janice Straight
Government Information Specialist—Branch 2
Division of Information Disclosure
Office of Disclosure, Information Governance, and Accessibility
Office of Management and Enterprise Services
Office of the Commissioner
U.S. Food and Drug Administration

U.S. Food & Drug Administrator
10903 New Hampshire Avenue
Silver Spring, MD 20903

www.fda.gov

EXHIBIT A-2

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

Table of Contents

SUMMARY.....1

ADMINISTRATIVE DATA.....2

HISTORY.....4

INTERSTATE (I.S.) COMMERCE.....5

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED).....7

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED.....8

FIRM'S TRAINING PROGRAM.....8

MANUFACTURING/DESIGN OPERATIONS.....9

MANUFACTURING CODES.....12

RECALL PROCEDURES.....12

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE.....13

ADDITIONAL OBSERVATIONS.....13

REFUSALS.....13

GENERAL DISCUSSION WITH MANAGEMENT.....14

ADDITIONAL INFORMATION.....15

SAMPLES COLLECTED.....15

VOLUNTARY CORRECTIONS.....15

EXHIBITS COLLECTED.....16

ATTACHMENTS.....16

SIGNATURE.....18

Establishment Inspection Report**FEI:** 3011941572

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

SUMMARY

Assessment	
Operation ID and Name	290790: FY24 OPMS Kratom Death Complaint Assignment

Summary Data	
This is a comprehensive report.	
Inspection Basis	Consumer Complaint
Inspection Basis Comment	The current inspection was initiated as comprehensive inspection, as a result of following up on a consumer complaint regarding O.P.M.S Black Liquid Kratom. The complaint was associated with O.P.M.S Black Liquid Kratom, lot [REDACTED]. O.P.M.S Black Liquid Kratom lot [REDACTED] was associated as being distributed by A1 Wholesale and the Beeman Ave location.

Summary
This FDA inspection, FY24 OPMS Kratom Death Complaint Assignment, was initiated as a comprehensive inspection, as a result of following up on a consumer complaint regarding O.P.M.S Black Liquid Kratom, conducted under Operation ID #290790. The inspection was conducted in accordance with limited scope Preventive Controls (PC) (DFPG# 19-03) to determine the firm's compliance in accordance with 21 CFR 117 and CPGM 7303.040 Preventive Controls in Human and Animal Foods, covering Subparts A, B, and F. This inspection is their first initial FDA inspection. The firm currently acts as an ambient warehouse and distributor of various kratom products including O.P.M.S Black Liquid Kratom. At the time of the inspection the firm did not [REDACTED] (b)(3) 21 U.S.C. § 350d(a)(5)). The current inspection covered the firm's storage and distribution of O.P.M.S Black Liquid Kratom. Documents reviewed include receiving, storing, sanitation, shipping operations, and employee training records. During the inspection on 08/27/2024, O.P.M.S. Black Liquid Kratom lot #2194 sealed cartons were examined. Refer to Exhibit #1 for incoming Bill of Lading (BOL) for lot 2194 and Exhibit #2 for an outgoing BOL of lot 2914. At the conclusion of the inspection a one-item FDA 483, Inspectional Observation, was issued for: [REDACTED] (b)(3) 21 U.S.C. § 350d(a)(5)). Additionally, the following items were observed and discussed with management; a leaking pipe on the warehouse floor, logging batch numbers, and distributing kratom products. Management was informed that any conditions discussed during the inspection and close-out meeting may be considered violations of the Food, Drug and Cosmetic Act after review by the Agency and legal sanctions including warning letters, import alerts, refused entry or withdrawal of registration are available to FDA if an establishment does not voluntarily correct serious conditions. Management

Establishment Inspection Report**FEI: 3011941572**

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

Summary

stated a written response will be submitted.

Two samples, #1268589 and 1268590, were collected during the inspection, each comprising of one sealed carton of O.P.M.S. Black Liquid Kratom lot #2194. Each sealed carton contains 50 individually sealed 8.8ml bottles. Additionally, sample 1263056, an affidavit of Mr. David Gabbay, is a documentary sample to capture responsibility and interstate, was also collected during the inspection. Refusals for information were experienced during the inspection, refer to Refusals section of the report for more information. Refusals for information were experienced during the inspection, refer to Refusals section of the report for more information.

Program Assignment Codes Covered

Program Assignment Code	Program Assignment Title
03040	FOOD CGMP INSPECTIONS
03040L	LIMITED SCOPE PCHF INSPECTIONS

Summary of Discussion Items Not on FDA Form 483 - Current Inspection

CFR Number	Citation Text	Correction Status
(b)(3) 21 U.S.C. § 350d(a)(5)		No Firm Response Submitted

Correction Statuses current at time report was signed.

Consumer Complaints Review

During the inspection, Mr. Gabbay stated A1 Wholesale does not have a procedure written for Complaints. Mr. Gabbay stated that in the event of a complaint, much like a recall, that Martain Sales would have the information regarding lots sent to distributors, and that all complaint processes / recall processes would go through Martain Sales. On 08/28/2024, I requested complaint documents, however, Mr. Gabbay did not provide any complaints during the inspection.

Per Mr. Gabbay, the firm was not aware of any adverse event complaints, including the complaint which initiated this inspection. However, he stated that there are "ambulance chasers who were legally going those involved with O.P.M.S." but did not say if A1 was involved with such proceedings.

Inspection Samples

Sample Number(s)	1268589; 1268590
------------------	------------------

ADMINISTRATIVE DATA

Establishment Inspection Report**FEI:** 3011941572

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

Administrative Data	
Firm	Jopen LLC, d.b.a A1 Wholesale
Physical Address	
Address Line 1	4949 Beeman Ave
City / State / ZIP	Dallas, TX 75223-3012
Mailing Address	
Address Line 1	3200 Broadway Blvd Ste 530
City / State / ZIP	Garland, TX 75043-1571
Inspection Date(s)	8/27/2024, 8/28/2024, 8/29/2024

FDA Inspection Participants	
Participant Name and Title	
Sara Valenzuela, Investigator	
Brook Shea, Investigator	

Issued 482 Forms	
On the date(s) below, credentials were presented and a "Form FDA 482, Notice of Inspection" (attached) was issued to the person listed.	
Date Issued	Issued To
8/27/2024	David Gabbay, Manager

FDA Credentials Were Displayed to the Following Person(s)	
Person's Name and Title	David Gabbay, Manager

FDA Form 483		
Description	Date Issued	Issued To
Original	Aug 29 2024 01:45PM	David E. Gabbay, Manager

FMD-145 Recipient and Industry Portal Representative/Most Responsible Corporate Official*			
IPR/FMD Person			
Person's Name and Title	David Gabbay, Manager		Industry Portal Representative and FMD-145 Recipient
Email Address	(b)(6) (b)(7)(C)		
Mailing Address	3200 Broadway, Suite 530, Garland, TX 75043		
Phone Number	(b)(6) (b)(7)(C)		
*If a corporation			

Guidance Documents Given to the Firm	
On 08/27/2024, I, Investigator Brook Shea, and Investigator Sara Valenzueal, displayed our FDA credentials and issued the Form FDA 482 - Notice of Inspection to David Gabbay, who identified himself as the most responsible person at the firm at the time of the inspection. We were accompanied by Mr. Gabbay and Mr. (b)(4), legal counsel for A1 Wholesale, throughout the duration of the inspection.	

Establishment Inspection Report**FEI:** 3011941572

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

Guidance Documents Given to the Firm

FMD-145 and FDA post-inspectional correspondence should be sent to:

Mr. David Gabbay, Manager
Jopen LLC, d.b.a A1 Wholesale
3200 Broadway Blvd, Ste 530
Garland, TX 75043

(b)(6) (b)(7)(C)

Mr. Gabbay requested an additional FMD-145 be sent via email to his legal counsel,

Mr.

(b)(4)

(b)(6) (b)(7)(C)

I provided Mr. Gabbay a list of FDA web links to the following documents and Electronic Submission of Correspondences HAFW3 Memorandum:

FDA Food Safety Modernization Act (FSMA)

Key Requirements: Accredited Third-Party Certification

Key Requirements: Preventive Controls for Human Food

Key Requirements: Preventive Controls for Animal Food

Key Requirements: Intentional Adulteration Mitigation Strategies

Key Requirements: Registration of Food Facilities

Key Facts: Preventive Controls for Human Food

Key Requirements: Foreign Supplier Verification Programs

Reportable Food Registry (RFR) At A Glance Fact Sheet

Key Requirements: Sanitary Transportation, Human and Animal Food

Fact Sheet: Voluntary Qualified Importer Program

FDA.GOV

Additionally, Mr. Gabbay was informed of supplemental kratom information found on the FDA website.

HISTORY

Food Firm Registration Status	None
Hours of Operation	Hours at the Beeman Ave location are approximately 9am - 4:30pm, Monday through Friday, as per the signage on the receiving door.
Legal Status	LLC
Additional Information	This report was written by Investigator Shea, unless otherwise noted. Upon our initial arrival, at approximately 10:00am CST at the 4949 Beeman Ave location, Investigator Valenzuela and myself were greeted by Ms. (b)(6) (b)(7)(C), Manager of A1 Wholesale and (b)(6) (b)(7)(C). When

Establishment Inspection Report**FEI: 3011941572**

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

asked what was the legal name of the firm, in order to fill out the FDA 482, Notice of Inspection, [REDACTED] stated she could not provide a response and left the room. An hour later, 11:00am CST, Mr. David Gabbay, Manager of A1 Wholesale and [REDACTED], and Mr. [REDACTED], legal counsel to A1 Wholesale, arrived. The 482 was issued to Mr. Gabbay and the inspection began.

Per Mr. Gabbay [REDACTED] and Jopen, LLC, are doing business as A1 Wholesale; a distributor of various kratom products including O.P.M.S Black and Gold Liquid Kratom.

Additionally, A1 Wholesale contracts space from [REDACTED] [REDACTED] A1 Wholesale also contracts [REDACTED] to fulfill their order reception, holding, and shipment of kratom based products, **(General Discussion)**. The [REDACTED] is located at [REDACTED]. A1 Wholesale has offices located at 3200 Broadway, Suite 530, Garland, TX 75043. These offices do not store any products.

Per Mr. Gabbay, A1 Wholesale handles various kratom products, including O.P.M.S. Black Liquid Kratom. Per Mr. Gabbay, O.P.M.S. is supplied by Nuza, LLC, whom he believes is the manufacturer of the products. Mr. Gabbay also stated that O.P.M.S. products, including O.P.M.S. Black Liquid Kratom, is owned by Martain Sales. Mr. Gabbay also stated that A1 Wholesale contains a contract with Martain Sales, which was not supplied during the inspection when asked on 08/28/2024. During the inspection, when clarifications were needed regarding O.P.M.S. lot codes, Mr. Gabbay communicated with Mr. Mark Reilly, of Martain Sales, presumably located in Georgia.

On the O.P.M.S. Black Liquid Kratom products, Choice Organics is identified as a distributor. Mr. Gabbay stated he had created the phone number and the email address associated with Choice Organics, per a request by Martain Sales. Once the phone number and email address was created, this information was provided back to Martain Sales. Mr. Gabbay explained he is no longer involved with Choice Organics.

INTERSTATE (I.S.) COMMERCE

Description of Interstate Commerce	Per Mr. Gabbay, all products handled by the firm are ambient temperature, shelf stable finished goods. The firm receives approximately
------------------------------------	--

Establishment Inspection Report**FEI: 3011941572**

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

	... of its products from outside of Texas, and approximately ... of all products are shipped out of Texas. A1 Wholesale receives orders such as O.P.M.S. Black Liquid Kratom over the phone with Partynuts.com. To order from Partynuts.com a customer is to be vetted first, to ensure they are a business. This is done in a variety of ways including verifying tax ID's, the business' locations, etc. These sales are managed by ..., a contracted third party ordering system. A1 Wholesale's ordering software is then updated by ... with the order details. The orders are then passed to ... for their employees to pack and ship orders. Orders are packed and shipped with A1 Wholesale documentation. Orders are shipped ... using ... trailers to customers. ..., on behalf of A1 Wholesale, distributes finished products nationwide. On 08/27/2024, I observed A1 Wholesale contained finished product lot 2194 of O.P.M.S. Black Liquid Kratom, in stock at the ... facility. Refer to Exhibit #1 for an incoming BOL and Exhibit #2 or an outgoing BOL for O.P.M.S. Black Liquid Kratom lot 2194, shipped on 08/13/2024 to a customer in Per Mr. Gabbay, the firm who supplies the O.P.M.S. Black Liquid Kratom, Nuza, LLC, is located in Georgia. Prior to 2016, Nuza would provide BOLs stating their shipping address, but since 2023, they have began providing blind BOLs, which do not include the name of the shipper or receiver of goods. Additionally, these BOLs do not include the lot number or description of what products are being shipped. Per Mr. Gabbay, he contacted Nuza, LLC in order to obtain the incoming BOL and confirmed that the BOL supplied, # ..., was the BOL for lot 2194. The BOL provided by Mr. Gabbay for this outgoing lot, BOL# ..., does not include lot numbers or a product description citing what products were included in the order. Per Mr. Gabbay, there is no ... system to track what lot numbers are associated with incoming and outgoing shipments (General Discussion). Per Mr. Gabbay, he contacted Nuza, LLC to verify that the outgoing BOL provided was also lot 2194. Refer to Attachment #3, for an Affidavit including this information.
--	---

Product Covered	O.P.M.S. Black Liquid Kratom lots ... and 2194.
Incoming	Yes
Received From	A1 Wholesale receives orders of O.P.M.S. Black Liquid Kratom from Nuza, LLC. Mr. Gabbay provided Bill of Lading# ..., shipped from Nuza, LLC, located at ... , on 09/07/2023, for O.P.M.S. Black Liquid Kratom lot # ... (

Establishment Inspection Report**FEI: 3011941572**

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

	Exhibit #3). Mr. Gabbay contacted Nuza, LLC in order to obtain incoming BOLs. Per Mr. Gabbay, Nuza, LLC confirmed to him that Bill of Lading# (b)(4), shipped from Nuza, LLC on 09/07/2023, is for the O.P.M.S. Black Liquid Kratom lot # --. The O.P.M.S. Black Liquid Kratom product is received in finished product form and A1 Wholesale does not manipulate the product further. Mr. Gabbay provided Bill of Lading# (b)(4) for the current batch of O.P.M.S. Black Liquid Kratom in inventory at the Beeman Ave location, lot# 2194 (Exhibit #1). The BOL states that both the ship from and ship to address as the Beeman Ave location, as a blind BOL. Nuza, LLC began utilizing blind BOLs in 2023, that no longer state their name as the shipper. Mr. Gabbay contacted Nuza, LLC and stated that they confirmed Bill of Lading# (b)(4) was shipped from Nuza, LLC, and is for the O.P.M.S. Black Liquid Kratom lot #2194. No date and amount is listed on the BOL. Refer to Attachment #3 for more information.
Outgoing	Yes
Sent To	Mr. Gabbay provided BOL# (b)(4) shipped from the Beeman Ave location on 10/18/2023 to a customer in (b)(6) (Exhibit #4). The outgoing BOL provided was an A1 Wholesale shipping document contracted to --. Mr. Gabbay contacted Nuza, LLC confirmed that Bill of Lading# (b)(4), is for the O.P.M.S. Black Liquid Kratom lot # --. No amount or description of O.P.M.S. Black Liquid Kratom is on the BOL. Mr. Gabbay BOL# (b)(4) shipped from the Beeman Ave location on 08/13/2024 to a customer in (b)(6) (Exhibit #2). The outgoing BOL provided was an A1 Wholesale shipping document contracted to --. Mr. Gabbay contacted Nuza, LLC to confirm that Bill of Lading# (b)(4) is for the O.P.M.S. Black Liquid Kratom lot #2194. No amount or description of O.P.M.S. Black Liquid Kratom is on the BOL. Refer to Attachment #3 for more information.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Description of Jurisdiction	Per Mr. Gabbay, the firm A1 Wholesale is a distributor of various kratom products including O.P.M.S Black Liquid Kratom. A1 Wholesale contracts space from (b)(4)
-----------------------------	--

Establishment Inspection Report**FEI: 3011941572**

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

	(b)(4) and contracts for (b)(4) to fulfill their order reception, holding, and shipment of products. Mr. Gabbay did not provide a list of products that A1 Wholesale distributes. Refer to Exhibit #12 for photos of some of the products stored at (b)(4), for A1 Wholesale. Product sales via distribution are made via (b)(4) wholesale. Refer to Exhibit #5 for A1 Wholesale's top three customers.
--	---

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	David Gabbay, Manager
Roles and Authorities	Per Mr. Gabbay, he is the Manager of (b)(4) and Jopen LLC, doing business as A1 Wholesale, a distributor of various kratom products including O.P.M.S Black Liquid Kratom. His daily job tasks include managing contracts with customers and vendors. He has the ability to handle orders and product ordering. From approximately 2013 to 2016, he would contact Mr. Mark Reilly, of Martian Sales, located in Georgia, directly via a phone call to place orders for O.P.M.S. products. From approximately 2016 onward, O.P.M.S. products are (b)(4) shipped to A1 Wholesale without the need of Mr. Gabbay placing orders. Mr. Gabbay only has (b)(4) report, (b)(4), an on-site A1 Wholesale and (b)(4) Manager at the Beeman Ave, location. Per Mr. Gabbay, he reports directly to the Jopen, LLC trust. Mr. Gabbay refused to state who makes up the the Jopen, LLC trust, and who in the trust he reports to. He also has an unlimited budget authority to make changes to A1 Wholesale, and has the duty and power to detect, prevent and correct food safety violations.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Industry Portal Representative, FMD 145 Recipient, Accompanied During the Inspection
Email Address	(b)(6) (b)(7)(C)
Mailing Address	3200 Broadway, Suite 530, Garland, TX 75043
Phone Number	(b)(6) (b)(7)(C)

FIRM'S TRAINING PROGRAM

Prior to 2024, when A1 Wholesale began it's contract with (b)(4), the firm contained a training procedure, **Exhibit #9**. Per Mr. Gabbay, employees received on the job experience, and were

Establishment Inspection Report**FEI: 3011941572**

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

trained upon hire for their responsibilities, and the GMPs for the facility. Mr. Gabbay did not provide training logs or verification actions prior to the 2024 contract. Mr. Gabbay stated that he believes these procedures are being followed by [REDACTED], and that employees still practice this procedure for training.

MANUFACTURING/DESIGN OPERATIONS**Process Flow, Operations, and Product Coverage**

Per Mr. Gabbay, from approximately 2013 through 2024, A1 Wholesale maintained their own processes for receiving, storing / warehousing, and distributing products. During this time A1 Wholesale utilized a variety of procedures, such as:

Inventory receiving, **Exhibit #6**

Inventory storage, **Exhibit #7**

Inventory shipping, **Exhibit #8**

Employee Training, **Exhibit #9**

Sanitation, **Exhibit #10**

Pest Control, **Exhibit #11**

A1 Wholesale did not maintain any verification actions / logs of these actions during this time period. The inspection of the facility focused on the process flow of O.P.M.S. Black Liquid Kratom.

As of 02/11/2024, A1 Wholesale contracts space from [REDACTED] and contracts [REDACTED] to fulfill their order reception, holding, and shipment of products. [REDACTED] is located at [REDACTED]. A1 Wholesale has offices located at 3200 Broadway, Suite 530, Garland, TX 75043. These offices do not store any products. Mr. Gabbay is a Manager for both [REDACTED] and A1 Wholesale. Per Mr. Gabbay, [REDACTED] is not related to Jopen, LLC or to A1 Wholesale.

On 08/28/2024, Mr. Gabbay provided the contract between A1 Wholesale and [REDACTED]. The contract outlines specific activities [REDACTED] is to complete on behalf of A1 Wholesale. The following is excerpted directly from the contract:

(b)(4)

Establishment Inspection Report**FEI: 3011941572**

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

Process Flow, Operations, and Product Coverage

(b)(4)

The contract between A1 Wholesale and [REDACTED] was observed by Investigators Shea and Valenzuela but a copy was not permitted. The contract is for [REDACTED] and the contract agreement was signed off by Mr. Gabbay as both authorized signatory for [REDACTED] and A1 Wholesale, dated 02/12/2024.

Per Mr. Gabbay, A1 Wholesale does not have a contract with Nuza, LLC, the manufacturer of O.P.M.S. Black Liquid Kratom. However, Mr. Gabbay stated there is a contract between A1 Wholesale and Martian Sales. After my request for this contract, Mr. Gabbay refused to provide a copy. Additionally, Mr. Gabbay stated that there is no legal affiliation between Martain Sales and [REDACTED], per his knowledge.

Mr. Gabbay stated that his [REDACTED] report, [REDACTED] and the [REDACTED] employees are all staffed by a third-party company. Mr. Gabbay did not state the name of the staffing company.

From approximately 2013 to 2016, Mr. Gabbay would contact Mr. Mark Reilly, of Martian Sales, located in Georgia, directly via a phone call to place orders for O.P.M.S. products. From approximately 2016 onward, O.P.M.S. products are [REDACTED] shipped to A1 Wholesale without the need of Mr. Gabbay placing orders. Mr. Gabbay did not explain further as to how this works.

Per Mr. Gabbay, the products received at the Beeman location arrive in finished product form. They arrive on [REDACTED] trailers. These [REDACTED] trailers are contracted by their suppliers on a website that compares the [REDACTED] rates. This process is also followed when the products are shipped from the Beeman facility. There is no set transportation contract with whom A1 Wholesale or [REDACTED] use to carry the products for distribution.

Establishment Inspection Report**FEI: 3011941572**

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

Process Flow, Operations, and Product Coverage

Neither A1 Wholesale or [redacted] add any manufacturing codes to the products they store and distribute. Per Mr. Gabbay, O.P.M.S. Black Liquid Kratom may also include a two to four digit code on their product labeling, in order to prevent their customers from redistributing products themselves. Mr. Gabbay gave the example, "[redacted]", but could not explain what it meant. Mr. Gabbay also could not explain when these products include these codes, or what lots of products include these codes.

Per Mr. Gabbay, approximately [redacted] of all products that A1 Wholesale stores at the Beeman location is O.P.M.S. products, and of that, [redacted] of those products is the O.P.M.S. Black Liquid Kratom. Per Mr. Gabbay, the turnaround time for O.P.M.S. Black Liquid Kratom is approximately [redacted]. The product is often out of stock and is back ordered up to [redacted] at times.

Additionally, Mr. Gabbay explained that a third party also handles billing, [redacted]. Per Mr. Gabbay, A1 Wholesale is not billed for products received via Nuza, LLC until they distribute them to their customers. A1 Wholesale sends payment to [redacted], from there Mr. Gabbay does not know where money is routed. Likewise, some of A1 Wholesale's customers are required to pay upon placing an order on Partynuts, while other customers pay when the product is received and sold at their location. Mr. Gabbay also clarified that certain customers are charged different rates.

On 08/27 and 08/28, Mr. Gabbay and [redacted] joined Investigators Shea and Valenzuela on a walkthrough of the Beeman warehouse. During the walkthrough a leaking air conditioning pipe was observed (**General Discussion**). Refer to **Exhibit #12** for A1 Wholesale areas of the Beeman location warehouse. During the walkthrough on 08/27, the current batch of O.P.M.S. Black Liquid Kratom in inventory at the Beeman Ave location lot# 2194, was observed. Shipments of the O.P.M.S Black Liquid Kratom come in sealed cartons of fifty 8.8ml bottles. Investigators Shea and Valenzuela requested an individual product label for an individual bottle of O.P.M.S Black Liquid Kratom from the sealed carton. Mr. Gabbay and [redacted] opened the lot 2194 carton and pulled out a bottle. The opened 2194 lot contained individual O.P.M.S. Black Liquid Kratom bottles contained a lot number [redacted] with black ink on the bottom of the bottles. Refer to **Exhibit #14** for the currently used product label for O.P.M.S Black Liquid Kratom sealed carton and individual bottles.

Likewise, Mr. Gabbay provided an old carton of O.P.M.S Black Liquid Kratom, lot [redacted] for viewing. The opened [redacted] lot contained individual O.P.M.S. Black Liquid Kratom bottles containing a lot number [redacted] with black ink on the bottom of the bottles. Refer to **Exhibit #13** for the previously used product label for O.P.M.S Black Liquid Kratom sealed carton and individual bottles. Per Mr. Gabbay, the label change occurred early 2024, and this change was due to labeling requirements. Mr. Gabbay did not explain further.

On 08/28/2024, Mr. Gabbay contacted Mr. Mark Reilly, of Martian Sales, regarding the difference in lot numbers per a sealed container and the bottles it holds. Mr. Reilly explained to Mr. Gabbay that he is aware of the two different lot numbers, and that Martian Sales has the ability to trace both a carton and bottle.

Per the individual bottles of O.P.M.S. Black Liquid Kratom lot [redacted], from the sealed cartons of lot 2194, the ingredients listed on the product is as follows: Mitragnyna Speciosa (Kratom),

Establishment Inspection Report**FEI: 3011941572**

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

Process Flow, Operations, and Product Coverage

Mitragynine, 7-Hydroxymitragynine, Other Alkaloids, Other Ingredients: water, ethyl alcohol, propylene glycol, corn syrup, natural and artificial stabilization agents. Likewise, these are the ingredients found on the O.P.M.S. Gold Liquid Kratom, also stored and distributed from the Beeman location, **Exhibit #15**.

Choice Organics is cited as the distributor on all observed O.P.M.S. products, including O.P.M.S. Black Liquid Kratom lot# 2194, [redacted]; O.P.M.S. Gold lot# [redacted] and O.P.M.S. Black Liquid Kratom lot# [redacted] and [redacted]. Per Mr. Gabbay, Choice Organics is a company that he helped create sometime around 2014 - 2016. He created the phone number and the email address associated with Choice Organics, per a verbal request by Martain Sales for labeling requirements. Once the phone number and email address were created, this information was provided back to Martain Sales. Mr. Gabbay is no longer involved with Choice Organics, but explained that the current Choice Organics name was a d.b.a, and he does not know the legal name of the firm. Additionally, he believes that a third party now operates Choice Organics, but he does not know who this third party is.

Mr. Gabbay also clarified that the O.P.M.S. Black Liquid Kratom product label changed in early 2024. The formula and ingredients found on the O.P.M.S. Black Liquid Kratom label has not changed, per Mr. Gabbay, he believes the label changed for legal reasons, but did not know what the reasons were. Refer to **Exhibit #13** for the pre-2024 label of O.P.M.S. Black Liquid Kratom, and **Exhibit #14** for the post-2024, current, label of O.P.M.S. Black Liquid Kratom.

MANUFACTURING CODES

Per Mr. Gabbay, the products received at the Beeman location arrive in finished product form. Neither A1 Wholesale or [redacted] add any manufacturing codes to the products they store and distribute. Per Mr. Gabbay, O.P.M.S. Black Liquid Kratom may also include a two to four digit code on their product labeling, in order to prevent their customers from redistributing products themselves. Mr. Gabbay gave the example, "[redacted]", but could not explain what it meant. Mr. Gabbay also could not explain when these products include these codes, or what lots of products include these codes.

RECALL PROCEDURES

The firm does not have a standard operating procedure for recalls. The firm has never participated in a mock recall. Mr. Gabbay stated that in the event of a complaint, much like a recall, that Martain Sales would have the information regarding lots sent to distributors, and that all complaint processes / recall processes would go through Martain Sales. Mr. Gabbay stated that he would also mass email all of A1 Wholesale customers in order to let them know of a recall.

Establishment Inspection Report**FEI:** 3011941572

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**Additional Information**

Firm was made aware of one citation for: At the time of the inspection the firm does not contain a

(b)(3) 21 U.S.C. § 350d(a)(5)

The firm was made aware that this citation is not printable. Mr. Gabbay and (b)(4) understood this citation and stated that they will have the business registered. No time frame was provided.

ADDITIONAL OBSERVATIONS**Observations Not Listed on FDA Form 483**

Observation	1
Citation Text	Your food facility is not (b)(3) 21 U.S.C. § 350d(a)(5).
Observation Details	Specifically, at the time of the inspection the firm does not contain a (b)(3) 21 U.S.C. § 350d(a)(5)
Citation Reference	21 CFR 1.225
Correction Status	No Firm Response Submitted

REFUSALS**Inspection Refusals**

Other, please explain

During the inspection a variety of information was refused to Investigators Shea and Valenzuela, this includes:

2023 (b)(4) for A1 Wholesale.

Who is the Jopen, LLC trust, who in the trust does Mr. Gabbay report to.

Contracts between A1 Wholesale and Nuza, LLC.

Contracts between A1 Wholesale and Martain Sales.

A full product list for the products received, stored, and distributed by A1 Wholesale.

Who supplies A1 Wholesale / whom they receive their products from.

An affidavit was presented on 08/29/2024 to Mr. Gabbay. The affidavit was made available for

EI Start: 08/27/2024

EI End: 08/29/2024

GENERAL DISCUSSION WITH MANAGEMENT

On 08/29/2024, Mr. David Gabbay, Manager, and [REDACTED], Legal counsel for A1 Wholesale, in addition to Investigators Shea and Valenzuela, were present during the closeout meeting. At the time of the inspection the firm did not contain a [REDACTED] (**Observation #1**). The following points were discussed with Mr. Gabbay and [REDACTED]:

Leaking pipe:

During our inspection, we observed a leaking air conditioning pipe in the warehouse. Although the pipe was not leaking directly over product, I explained to Mr. Gabbay that if product were to be involved, that there was a chance that products could be affected, depending on their product packaging.

Response: Mr. Gabbay understood this observation and stated that there was a maintenance ticket submitted for the pipe. Upon a walkthrough conducted on 08/28/2024, it appeared the pipe had been fixed.

Logging Batch Numbers:

During our inspection, we observed that A1 Wholesale does not record lots of products that are received, stored, and distributed from the facility. We explained how the lack of this information could affect A1 Wholesale in the event of a complaint or recall.

Response: Mr. Gabbay understood my observation and stated that he is looking into adding lot information to packing slips that A1 Wholesale could provide their customers.

Likewise, a discussion was had regarding violative / adulterated products due to kratom. I explained to Mr. Gabbay and (b)(4) that the FDA does not recognize kratom as an ingredient to be used in food items. I explained to them that although they are not the manufacturers of this product, there is still responsibility because they are distributing this product. I explained to them guidance available on the FDA website regarding kratom. Mr. Gabbay and (b)(4) provided no comment regarding this information.

During the close out meeting, we thanked them for their time and concluded the inspection. We explained to them the authority of the FDA and that the firm must ensure that they continue to abide by the Food Drug & Cosmetic Act. We explained to them that the observations discussed during the inspection are our observations and after further review of inspectional information, the items listed may be determined as violations of Food, Drug and Cosmetic Act. Further, legal

Establishment Inspection Report**FEI: 3011941572**

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

sanctions under the Food, Drug, and Cosmetic Act may include seizure, injunction, prosecution, civil money penalties, and other penalties, if the firm does not voluntarily correct serious conditions. We also mentioned the FDA Website and that information and clarification about regulations is readily available there and reminded them of the Dallas District Memo we had provided them earlier with contact information for the HAFW3 Director. Likewise, we provided them of the FDA website regarding kratom. Additionally, I advised them that FDA recommends the firm responds within fifteen (15) business days after receiving FDA 483 Inspectional Observations. We asked them if they had any questions concerning the inspection, to which they replied that they had none. Since there were no questions, we thanked both Mr. Gabbay and Mr. [REDACTED] and closed the inspection.

ADDITIONAL INFORMATION

The officially sealed original copy and unsealed working copy discs containing the photographs taken during the inspection are filed with the unlabeled exhibits and attachments.

SAMPLES COLLECTED

Sample Number	1268589
Description	One sealed carton of O.P.M.S. Black Liquid Kratom from inventory at the Beeman Ave location, lot# 2194. Shipments of the O.P.M.S Black Liquid Kratom come in sealed cartons of fifty 8.8ml bottles. Per Mr. Gabbay, this shipment has come directly from Nuza, LLC and has not been manipulated by A1 Wholesale or [REDACTED].
Sample Number	1268590
Description	One sealed carton of O.P.M.S. Black Liquid Kratom from inventory at the Beeman Ave location, lot# 2194. Shipments of the O.P.M.S Black Liquid Kratom come in sealed cartons of fifty 8.8ml bottles. Per Mr. Gabbay, this shipment has come directly from Nuza, LLC and has not been manipulated by A1 Wholesale or [REDACTED].
Sample Number	1263056
Description	Sample 1263056, an affidavit of Mr. David Gabbay, is a documentary sample to capture responsibility and interstate, was also collected during the inspection.

VOLUNTARY CORRECTIONS

No voluntary corrections made as this was the firm's first FDA inspection.

Establishment Inspection Report**FEI: 3011941572**

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	Description	Number of Pages
1	O.P.M.S. Black Liquid Kratom lot #2194 BOL Incoming	1
2	O.P.M.S. Black Liquid Kratom lot #2194 BOL Outgoing	1
3	O.P.M.S. Black Liquid Kratom lot # BOL Incoming	1
4	O.P.M.S. Black Liquid Kratom lot # BOL Outgoing	1
5	A1 Wholesale Top 3 Customers	1
6	A1 Wholesale Incoming Receiving Procedure	2
7	A1 Wholesale Incoming Storage Procedure	2
8	A1 Wholesale Shipping Procedure	1
9	A1 Wholesale Employee Training Procedure	1
10	A1 Wholesale Sanitation Procedure	2
11	A1 Wholesale Pest Control Procedure	2
12	Photos of the A1 Wholesale Section of Warehouse	72
13	Previous O.P.M.S. Black Liquid Kratom Label - Pre 2024	14
14	Current O.P.M.S. Black Liquid Kratom Label Post-2024	17
15	Current O.P.M.S. Gold Liquid Kratom	12

ATTACHMENTS

Attachments		
Attachment Number	Description	Number of Pages
	FDA 482 Notice of Inspection issued to Mr. David Gabbay, Manager of Jopen, LLC d.b.a. A1 Wholesale on 08/27/2024.	3
1	Issued 483	2
3	FDA Form 463a - Affidavit of Mr. David Gabbay, Manager of Jopen, LLC d.b.a. A1 Wholesale on 08/29/2024.	4
4	Documentary sample (1263056) of Affidavit of A1 Wholesale Manager, David Gabbay.	2

Establishment Inspection Report**FEI: 3011941572**

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

Attachments		
Attachment Number	Description	Number of Pages
5	Receipt for Samples, 1268590 and 1268589	1
6	Completed Sample Collection Report (1268590)	25
7	Completed Sample Collection Report (1268589)	25

Establishment Inspection Report

FEI: 3011941572

Jopen LLC, d.b.a A1 Wholesale

EI Start: 08/27/2024

Dallas, TX 75223-3012

EI End: 08/29/2024

SIGNATURE

Brook
Shea -S
Digitally signed by
Brook Shea -S
Date: 2024.09.06
09:57:38 -05'00'

Sara A.
Valenzuela -S
Digitally signed
by Sara A.
Valenzuela -S
Date: 2024.09.06
09:53:10 -05'00'

EXHIBIT A-3

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314			DATE(S) OF INSPECTION 8/27/2024-8/29/2024 FEI NUMBER 3011941572		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED David E. Gabbay, Manager					
FIRM NAME Jopen LLC, d.b.a Al Wholesale			STREET ADDRESS 4949 Beeman Ave		
CITY, STATE, ZIP CODE, COUNTRY Dallas, TX 75223-3012			TYPE ESTABLISHMENT INSPECTED Warehouse		
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.					
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:					
X Brook Shea Investigator Signed By: 2002001165 Date Signed: 08-29-2024 12:45:19					
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Brook Shea, Investigator Sara A Valenzuela, Investigator		DATE ISSUED 8/29/2024 Sara A Valenzuela Investigator Signed By: Sara A Valenzuela-G Date Signed: 08-29-2024 12:44:54 X	
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 of 1 PAGES					

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

EXHIBIT A-4

For Sample Number: 1268589

This is an accurate reproduction of the original electronic record as of 09/05/2024

Flag	Flag Remarks
Episode Number	Origin
	Domestic
FEI	Basis
3032150939	Compliance
Compliance Num	Sample Type
	Official
Date Collected	FIS Smpl Num
08/28/2024	24339901
Product Code	Status
54KCE12	Completed
Responsible Firm	PAC
Manufacturer	21008
Country of Origin	Hours
United States	9
Related Smpl Num	Position Class
	INV
Sampling Organization	NDC Number
HAFW3	
Permit Number	Storage Rqrmnt.
	Ambient
Dealer is Consumer	Crx/DEA Schedule
No	
Recall Num	Consumer Compl. Num
Brand Name	
O.P.M.S.	

Product Description

Liquid kratom extract packaged in (See "Remarks")

Product Label

See continuation.

Reason for Collection

Collected per Compliance/For-cause sample collection of kratom product during establishment inspection on 8/27-29/2024 under assignmet ID: 12383921 and Op ID: 12446135 to be analyzed for quantitation of 7-OH Mitragynine and Mitragynine.

MFG Codes

"2194"

Expiration Date

No Exp Date

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
Jopen LLC, d.b.a A1 Wholesale	4949 Beeman Ave Dallas, TX 75223-3012	Dealer	3011941572	
Choice Organics	US			
	3680 Wilshire Blvd Ste P04-1084 Los Angeles, CA 90010-2709 US	Shipper	3027395753	
(b)(4)	(b)(4)	Shipper	(b)(4)	
Nuza, LLC	3075 Chastain Meadows Pkwy Marietta, GA 30066-3354 US	Manufacturer	3032150939	

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
(b)(4) of kratom extract	\$ (b)(4)	FDA484		

Description of Sample

Sample consists of (b)(4) of liquid kratom extract.

Method of Collection

See continuation.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"1268589 8/28/2024 SAV"

Collector's Identification on Seal

"1268589 9/3/2024 Sara A. Valenzuela, Investigator"

Sample Delivered To

UPS Store (b)(4), next day air, (See "Remarks")

Date Delivered

09/03/2024

Orig C/R & Records To

HAFE3

Lab w/Split Sample

0

Lab

DENLHAF

Date: 09/05/2024

Page: 1 of 4

For Sample Number: 1268589

This is an accurate reproduction of the original electronic record as of 09/05/2024

Document Number	Document Date	Document Type	Document Remarks
1	08/30/2024	Other	Assignment sheet for assign. ID: 12383921 and Op ID: 12446135 (2 pages)
2	08/27/2024	Other	FDA 482 - Notice of Inspection (3 pages)
3	08/29/2024	Other	FDA 484 - Receipt for Samples (2 pages)
4	08/28/2024	Other	Photos of product case labeling and FDA 484 - Receipt for Samples (8 pages)
5	08/13/2024	Bill of Lading	BOL for outgoing kratom product (2 pages)
6	08/29/2024	Affidavit	Affidavit (4 pages)

Remarks

See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	No	Yes	Sara A Valenzuela

Name of Signer	Date & Time of Signature	Meaning
Sara A Valenzuela	09/05/2024 12:35 PM ET	Collector
Sara A Valenzuela	09/05/2024 12:35 PM ET	Collector
Sara A Valenzuela	09/05/2024 11:27 AM ET	Collector

For Sample Number: 1268589

This is an accurate reproduction of the original electronic record as of 09/05/2024

Continuation:

Product Label

Front of case label reads in part "O.P.M.S. BLACK LIQUID".

Back of case label reads in part "LOT - 2194".

Top of case label reads in part "O.P.M.S. Distributed By: Choice Organics (213)-221-8049 Info@OPMSKratom.com
3680 Wilshire Blvd. Suite P04-111, Los Angeles, CA 90010".

UPC on back of case: 643375878777

Bottom of case label reads in part "O.P.M.S. KRATOM EXTRACT".

Method of Collection

On 8/28/2024, during establishment inspection of Jopen, LLC d.b.a. A1 Wholesale, located at 4949 Beeman Ave., Dallas, TX 75223, I collected 1 case, lot #2194, containing (b)(4) each of O.P.M.S. brand Black Liquid Kratom Extract. The case was enclosed in clear, plastic wrap; I left the case packaging intact for sample collection, preparation, and shipment. The sample contains the 702(b) portion.

During the inspection, Mr. David E. Gabbay, Manager, opened one of the cases from the same lot (2194) and one of the individual bottles CSO Shea and I examined and collected had an inkjet of (b)(4) printed on the bottom of the bottle. Mr. Gabbay was unsure if this was a separate lot number.

To ensure the uniformity of the same lot code, the sample collection focused on the outer packaging lot code; however, once the packaging is opened, it cannot be guaranteed the bottle lot code will match the outer packaging lot code. The firm could not explain this discrepancy as they are not the manufacturer. Mr. Gabbay provided the names of two different firms as the manufacturer, Martian Sales, Inc. (no location provided or located) and Nuza, LLC, located at 3075 Chastain Meadows Pkwy, Marietta, GA 30066.

A bill of lading (BOL) was collected for an outbound shipment of O.P.M.S. Black Liquid Kratom Extract by CSO Brook Shea. The BOL (b)(4), identifies (b)(4) as the shipper, ship date of 8/13/2024, shipped to (b)(4), located at (b)(4). There is no information contained within the BOL identifying the product, lot number, or amount. CSO Shea obtained an affidavit with information linking the BOL with the product, which Mr. Gabbay (the affiant) refused to sign on advice from council.

I transferred the sample via secure POV to my personal residence and stored it in a secure, locked room. On 8/29/2024, I transferred the sample via secure POV back to the firm in order to get clearer photographs of the case labeling. I transferred the sample back to my personal residence via secure POV and stored in a secure, locked room until I could prepare and ship the sample. At the close of the inspection on 8/29/2024, I issued a FDA 484 - Receipt for Samples to Mr. Gabbay, who provided the sample at no cost.

How Prepared

The sample was collected on 8/28/2024; however, I did not prepare or ship it until 9/3/2024. I was advised by DENLHAF that shipping after the Labor Day holiday would be ideal. The sample was held at my personal residence in a secure, locked room until preparation and shipment.

On 9/3/2024, I prepared the sample by placing a white, adhesive label bearing "1268589 8/28/2024 SAV" to the top, right of the

For Sample Number: 1268589

This is an accurate reproduction of the original electronic record as of 09/05/2024

Continuation:

product case. I then placed the sample inside of a large, unused whirl-pak bag, rolled the top of the bag down, and folded the wire tabs over to secure. I placed an official seal, dated 9/3/2024 over the rolled portion of the whirl-pak bag and then I taped a completed FDA 525 over the seal using clear, plastic tape.

I lined the bottom of a cardboard box with bubble wrap, wrapped the sealed sample in bubble wrap and then placed it in the cardboard box. The sample was placed in the same box as sample #1268590. I placed more bubble wrap around and on top of the sample and then sealed the cardboard box using clear, packing tape. I applied clear, packing tape along all edges of the box and then affixed a UPS shipping label to the top of the box.

I transported the sample via secure POV to UPS Store [REDACTED] (b)(4) and shipped it utilizing next day air to DENLHAF to be analyzed for quantitation of 7 - OH mitragynine and mitragynine. The sample was collected, prepared, and shipped in conjunction with sample #1268590. I maintained chain of custody of the sample at all times.

Remarks

Lab is aware of additional analysis requested per the discussion with Chad Whitwell, HAFW3 CO and Kim Dutzek OC/DE CO.

The 702(b) portion is included in the sample.

I took a photo of the original FDA 484 - Receipt for Samples due to the quality of the copy. Refer to document number 4.

The officially sealed original copy and unsealed working copy discs containing the photographs taken during the sample collection and inspection are filed with the unlabeled exhibits and attachments collected for the establishment inspection conducted 8/27-29/2024.

The sample was collected on 8/28/2024; however, due to the holiday weekend and on advice from DENLHAF, the sample was prepared and shipped on 9/3/2024

"Product Description" (continued): clear bottles with black, white, and green plastic wrap label and screw-on lid. Text on product bottle label in white, black, and green.

"Sample Delivered To" (continued): tracking [REDACTED] (b)(4).

Field Accomplishment And Compliance Tracking System (FACTS)**Assignment Sheet for:** Sara A. Valenzuela**Assignment ID:** 12383921**Operation ID:** 12446135**Type of Operation:** Domestic Sample Collection**Compliance Number:****Target Completion Date:** 09/30/2024**Requester Priority:** High**Scheduled Completion Date:****Organization Priority:****Subject:** Compliance/For-cause sample collection of kratom product**Background Information:****Requester's Remarks:****Work Remarks:****Investigator's Remarks:****Estimated Cost:****PAC(s):** 21008 DIETARY SUPPLEMENT SAMPLE COLLECTION AND ANALYSIS**Product:****Firm(s):****Consumer Complaints With Disposition
of 'Surveillance Information for next EI':****Requesting Organization:** HAFW3**Assignment POC Name:** Kristin N. Longfellow**Phone:** (214)253-5210**Fax:****Accomplishing Organization:** HAFW3**Performing Organization:** HAFW3-GRP5**Assignor:****Send samples to:****Other Assignee(s) on the Assignment within (HAFW3):**

=====

There are no other Assignees.

Field Accomplishment And Compliance Tracking System (FACTS)

Assignment Sheet for: Sara A. Valenzuela

District Use:

Firm POC Name:

There are no Points Of Contact

=====

Est Type

There are no Establishment Types

=====

Industry Code

There are no Industry Codes

=====

Registration Type

=====

Registration Date

=====

Profile Class

There are no Profile Classes

Last Covered Date Last Final Recommendation

There is no Last Covered Date

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT OFFICE ADDRESS & PHONE NO. 1701 Mann St Suite 1100 Dallas TX 75206 (214) 252 5200	
TO	2. NAME AND TITLE OF INDIVIDUAL David B. Gabbey Manager	3. DATE 08/27/2024	
	4. FIRM NAME Super LLC d.b.a. AI Wholesale	5. HOUR 11:01 a.m.	8. PHONE NO. & AREA CODE 469 185-2662
	6. NUMBER AND STREET 4749 Roman Ave		
	7. CITY AND STATE & ZIP CODE Dallas TX 75223		

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)]¹ and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264]²

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) (Food and Drug Administration Employee(s))	10. TYPE OR PRINT NAME(S) AND TITLE(S) (FDA Employee(s))
	Bruce Shea, CSO
	Sara A. Valenzuela, CSO

¹ Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information

described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this

(Continued on Reverse)

Act), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Sec. 704. (a)(2) The provisions of the third sentence of paragraph (1) shall not apply to (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice; (C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale; (D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Sec. 704. (a)(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records (A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or (B) required to be maintained under section 412.

Sec. 704(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, tobacco product, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

Sec. 704. (c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

Sec. 704. (d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m) (4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

²Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F – Licensing – Biological Products and Clinical Laboratories and* * * * *

Sec. 351(c) "Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation
(Continued on Page 3)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - *****Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than \$50, to furnish manufacturers of such

products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

Sec. 360 B.(a) It shall be unlawful—

(1) ***

(2) ***

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS & PHONE NUMBER 1201 Main St., Ste 7200 Dallas, TX 75202 214-2533-5200	
2. NAME AND TITLE OF INDIVIDUAL David E. Galtberg, Manager		3. DATE 8/29/2024	4. SAMPLE NUMBER 1268589 + 12688909
5. FIRM NAME Topen, LLC 10-b. 1234567890		6. FIRM'S DEA NUMBER N/A	
7. NUMBER AND STREET 44444 Berman Ave. Ave.		8. CITY AND STATE (Include Zip Code) Dallas, TX 75223	
9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification) The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and/or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form. (NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.) (b)(4) Black Liquid, sample # 1268589, Lot # 2194, 18th O.P.M.S. (b)(4) each of O.P.M.S. Black Liquid, sample # 1268590, Lot # 2194 (b)(4) Total sample cost (b)(4)			
10. SAMPLES WERE ☒ PROVIDED AT NO CHARGE ☐ PURCHASED ☐ BORROWED (To be returned)		11. AMOUNT RECEIVED FOR SAMPLE N/A ☐ CASH ☐ VOUCHER ☐ BILLED ☐ CREDIT CARD	
13. COLLECTOR'S NAME (Print or Type) Sara A. Valenzuela		12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge.) 	
14. COLLECTOR'S TITLE (Print or Type) Consumer Safety Officer		15. COLLECTOR'S SIGNATURE 	

Section 704 (c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] is quoted below:

"If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained."

Section 532(b) of The Federal Food, Drug and Cosmetic Act [21 U.S.C. 360 ii (b)] is quoted in part below:

"Section 532(b) In carrying out the purposes of subsection (a), the Secretary is authorized to-

- (1) ****
- (2) ****
- (3) ****

(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products"

21 Code of Federal Regulations 1307.02 is quoted below:

"1307.02 Application of State law and other Federal law.

Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such an act nor shall compliance with such be construed as compliance with other Federal or State laws unless expressly provided in such other laws."

Therefore, in the event any samples of controlled drugs are collected by FDA representatives in the enforcement of the Federal Food, Drug, and Cosmetic Act, the FDA representative shall issue a receipt for such samples on FDA Form 484, RECEIPT FOR SAMPLES, to the owner, operator, or agent in charge of the premises.

Report of analysis will be furnished only where samples meet the requirements of Section 704(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(d)] which is quoted below:

"Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge."

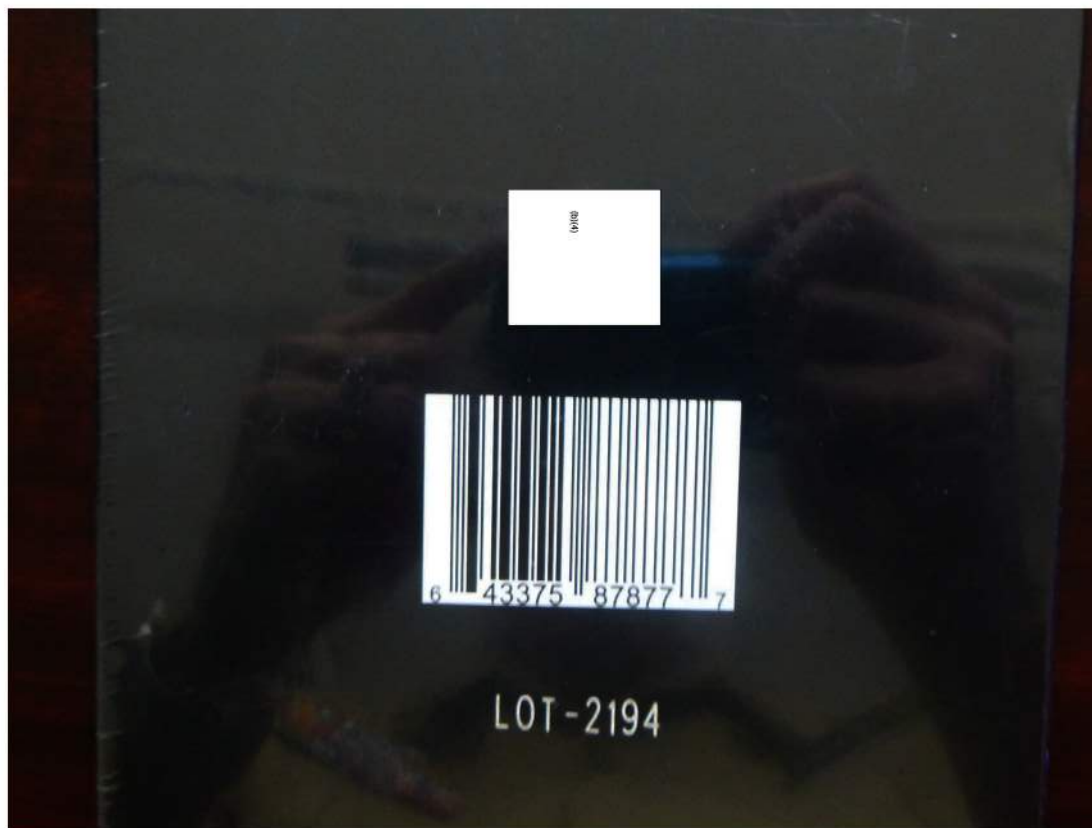








1268589 8/28/2024 SAV
Document 4, page 4 of 8





1268589 8/28/2024 SAV
Document 4, page 6 of 8



B

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1201 Main St., Ste 7240
Dallas, TX 75202
214-257-5200

David E. Gubbay, Manager
Tegen, LLC dba. As. Unwashed N/A
4444 Freeman Ave Dallas, TX 75227

8/28/2024 1268589 +
1268590

The following sample(s) were submitted for analysis to the Texas Department of Health and Human Services, Division of Food Safety, and the Texas Department of Health and Human Services, Division of Laboratory Sciences, for the purpose of testing for the presence of the following:

each of O.P.M.S.
Black Liquid, sample # 1268589, Lot # 2194,
each of O.P.M.S.
Black Liquid, sample # 1268590, Lot # 2194

Total Sample Cost

San Antonio Consumer Safety Office

RECEIPT FOR SAMPLES

1268589 8/28/2024 SAV
Document 4, page 8 of 8

STRAIGHT BILL OF LADING - SHORT FORM - ORIGINAL - NOT NEGOTIABLE

This form contains only the information necessary for the motor carrier to deliver, rate, and invoice the shipment described below.

Shipper: Ship Date 8/13/2024

(b)(4)
Dallas, TX 75223
Shipping
Reference Number:

(b)(4)

OWNERS SIGNATURE, ACKNOWLEDGES RECEIPT OF FREIGHT ON HAND AND RELEASES CARRIER FROM ALL LIABILITY FOR LOSS OR DAMAGE. SEPARATE CONTRACT, TERMS AND CONDITIONS ARE GOVERNED BY DOT, TARIFFS AND SHIPPER'S BILL OF LADING.

Consignee: Due Date 8/16/2024

(b)(4)
Reference Number:

Carrier:	(b)(4)
Pro#:	(b)(4)
Load#:	(b)(4)
BOL#:	(b)(4)

All Freight charges PPD/3rd party bill to:

(b)(4)

No. of Units & Container Type	NM	BASIC DESCRIPTION Identification Number (UN or NA), Proper Shipping Name, Hazard Class, Packing Group	NAFC	CLASS	Total Weight
1 Pallet		dietary supplement (42L 45/2 03H)	---	70	1050
*An X indicates hazardous material			Total weight (subject to correction)		1050

Shipper Special Instructions:

PMT

Consignee Special Instructions:**Comments:**

Guaranteed

NOTICE: Freight moving under this Bill of Lading is subject to classifications and tariffs established by the carrier and are available to shipper upon request. This notice supersedes and negates any claimed oral or written contract, promise, representation, or understanding between parties, except to the extent of any written contract signed by both parties to the contract.

Any unauthorized alteration or use of this bill of lading or the tendering of this shipment to any carrier other than that designated by company, may VOID company's obligations to make any payments relating to this shipment and VOID all rate quotes. All shippers, consignees, consignees, freight forwarders or freight brokers are jointly and severally liable for the freight charges relating to this shipment.

CUSTOMER AGREES TO THE ORGANIZATION'S TERMS AND CONDITIONS, WHICH CAN BE FOUND AT WWW.FREIGHTWAYCENTER.COM.

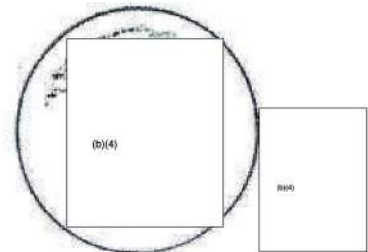
The Shipper certifies that the above-named materials are properly classified, described, marked, labeled and packaged, and are in proper condition for transportation according to the applicable regulations.

Shipper Signature X _____ Date: 8/13 Trailer# _____

Consignee Signature X _____ Date: _____ Seal# _____

Driver Signature X _____ Date: _____ Seal# _____

Permanent post-office address of shipper.



AFFIDAVIT		SAMPLE NO.
STATE OF Texas	COUNTY OF Dallas	
Before me, Brook Shea, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared David E. Gabbay in the county and state aforesaid, who, being duly sworn, deposes and says: I, David E. Gabbay, am the Manager of [REDACTED] and Jopen LLC, doing business as A1 Wholesale, a distributor of various kratom products including O.P.M. S Black Liquid Kratom. A1 Wholesale contracts space from [REDACTED] and for the [REDACTED] to fulfill their order reception, holding, and shipment of products. The [REDACTED] is located at [REDACTED]. A1 Wholesale has offices located at 3200 Broadway, Suite 530, Garland, TX 75043. These offices do not store any products. My daily job tasks include managing contracts with customers and vendors. I have the ability to handle orders and product ordering. From approximately 2013 to 2016, I would contact Mr. Mark Reilly, of Martian Sales, located in Georgia, directly via a phone call to place orders for O.P.M.S. products. From approximately 2016 onward, O.P.M.S. products are automatically shipped to A1 Wholesale without the need of me placing orders. I only have [REDACTED] report, [REDACTED], an on-site A1 Wholesale and [REDACTED] Manager at the [REDACTED] location. I report directly to the Jopen, LLC trust. I have an unlimited budget authority to make changes to A1 Wholesale, and I have the duty and power to detect, prevent and correct food safety violations. A1 Wholesale receives orders of O.P.M.S. Black Liquid Kratom from Nuza, LLC. On 08/28/2024, I provided CSO Shea Bill of Lading# [REDACTED], shipped from Nuza, LLC, located at 3075 Chastain Meadows Pkwy, Marietta, GA 30066, on 09/07/2023, for O.P.M.S. Black Liquid Kratom lot # [REDACTED]. The lot number and description of products included are not listed on our incoming Bills of Lading (BOL). There is no [REDACTED] tracking system for A1 Wholesale that documents what lot numbers of O.P. M.S. Black Liquid Kratom are received, stored, and shipped from the [REDACTED] location. I have to contact Nuza, LLC in order to obtain incoming BOLs. The incoming BOLs I provided to CSO Shea were provided to me by Nuza, LLC. Nuza, LLC confirmed to me that Bill of Lading# [REDACTED], shipped from Nuza, LLC on 09/07/2023, is for the O.P.M.S. Black Liquid Kratom lot # [REDACTED]. The O.P. M.S. Black Liquid Kratom product is received in finished product form and A1 Wholesale does not manipulate the product further. On 08/29/2024, I provided CSO Shea BOL# [REDACTED] shipped from the A1 Wholesale [REDACTED] location on 10/18/2023 to a customer in [REDACTED]. The outgoing BOL I provided to CSO		
AFFIANT'S SIGNATURE AND TITLE		
FIRM'S NAME AND ADDRESS (Include Zip Code)		
Jopen LLC d.b.a A1 Wholesale [REDACTED]		
Subscribed and sworn to before me at Dallas, TX , this 29 day of August , 20 24 . _____ (Employee's Signature)		
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.		

AFFIDAVIT		SAMPLE NO.
STATE OF Texas	COUNTY OF Dallas	
Before me, <u>Brook Shea</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared <u>David E. Gabbay</u> in the county and state aforesaid, who, being duly sworn, deposes and says: Shea was a A1 Wholesale shipping document. I contacted Nuza, LLC confirmed to me that Bill of Lading# <u>(b)(4)</u>, is for the O.P.M.S. Black Liquid Kratom lot # <u>---</u>. No amount or description of O.P.M.S. Black Liquid Kratom is on the BOL. A1 Wholesale receives orders for products, such as O.P.M.S. Black Liquid Kratom, from orders that are placed over the phone with Partynuts.com. To order from Partynuts.com a customer is to be vetted first, to ensure they are a business. This is done in a variety of ways including verifying tax ID's, the business' locations, etc. These sales are managed by <u>(b)(4)</u>, a contracted third party ordering system. A1 Wholesale's ordering software is then updated by <u>(b)(4)</u> with the order details. The orders are then passed to <u>(b)(4)</u> for their employees to pack and ship orders. Orders are packed and shipped with A1 Wholesale documentation. Orders are shipped via wholesale using third party trailers to customers. The current batch of O.P.M.S. Black Liquid Kratom in inventory at the <u>(b)(4)</u> location is lot# 2194. Shipments of the O.P.M.S Black Liquid Kratom come in sealed cartons of <u>(b)(4)</u> bottles. This lot, 2194, when opened, contained individual O.P.M.S. bottles containing the lot number <u>(b)(4)</u> with black ink on the bottom of the bottles. This lot, 2194, containing lot <u>---</u> bottles, was manufactured by Nuza, LLC. On 08/28/2024, I provided CSO Shea Bill of Lading# <u>(b)(4)</u>. The BOL states that both the ship from and ship to address as the <u>(b)(4)</u> location. Nuza, LLC began utilizing blind BOLs in 2023, that no longer state their name as the shipper. Nuza, LLC confirmed to me that Bill of Lading# <u>(b)(4)</u>, shipped from Nuza, LLC, is for the O.P.M.S. Black Liquid Kratom lot #2194. No date and amount is listed on the BOL. On 08/29/2024, I provided CSO Shea BOL# <u>(b)(4)</u> shipped from <u>(b)(4)</u> location on 08/13/2024 to a customer in <u>(b)(4)</u>. The outgoing BOL I provided to CSO Shea was a <u>(b)(4)</u> shipping document provided to A1 Wholesale. I contacted Nuza, LLC confirmed to me that Bill of Lading# <u>(b)(4)</u> is for the O.P.M.S. Black Liquid Kratom lot # <u>---</u>. No amount or description of O.P.M.S. Black Liquid Kratom is on the BOL. <u>#2194 85 08/29/24</u> The label for the sealed carton of O.P.M.S. Black Liquid Kratom is in part, "***O.P.M.S. BLACK		
AFFIANT'S SIGNATURE AND TITLE		
FIRM'S NAME AND ADDRESS (include Zip Code)		
Jopen LLC d.b.a A1 Wholesale <u>(b)(4)</u>		
Subscribed and sworn to before me at <u>Dallas, TX</u> (City and State)		
this <u>29</u> day of <u>August</u> , 20 <u>24</u> .		
_____ (Employee's Signature)		
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.		

AFFIDAVIT		SAMPLE NO.
STATE OF Texas	COUNTY OF Dallas	
Before me, <u>Brook Shea</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared <u>David E. Gabbay</u> in the county and state aforesaid, who, being duly sworn, deposes and says: LIQUID*** WARNING: Do not use product before reading product inserts, labels, warnings, directions, disclaimers, and agreeing to the terms & conditions, and notices. Visit www.OPMSKratom.com for all updates including full disclaimer, and terms & conditions*** Usage size: 1/2 bottle - 4.4 ml, Usage per bottle: 2*** Mitragyna Speciosa (Kratom)- per 4.4ml per bottle*** Leaf extract total content: <108 mg ≤ 216 mg*** Mitragynine : ≤68 mg ≤135 mg*** 7-Hydroxymitragynine: ≤ 1 mg ≤ 1 mg*** Other Alkaloids: ≤40 mg ≤40 mg*** Other Ingredients: water, ethyl alcohol, propylene glycol, corn syrup, natural and artificial stabilization agents*** Distributed By: Choice Organics (213)-221-8049*** Info@OPMSKratom.com 3680 Wilshire Blvd. Ste P04-1111 Los Angeles, CA 90010*** LOT - 2194***. UPC: 643375878777 " The individual bottle labels are stored in cardboard containers, their label in part, "****O.P.M.S. BLACK LIQUID KRATOM EXTRACT 8.8ml*** WARNING: Do not use product before reading product insert, labels, warnings, directions, disclaimers, and agreeing to terms & conditions, and notices. Visit www.OPMSKratom.com for all updates including full disclaimer, and terms & conditions.*** Distributed By: Choice Organics (213)-221-8049 Info@OPMSKratom.com 2680 Wilshire Blvd. Suite P04-111, Los Angeles, CA 90010****. 2144****. UPC: 650075995130 The individual bottles, out of the cardboard containers, their label in part, "****O.P.M.S. BLACK LIQUID KRATOM EXTRACT*** 8.8ml***Warning: Do not use product before reading product insert, labels, warnings, directions, disclaimers, and agreeing to terms & conditions, and notices. Visit www.OPMSKratom.com for all updates including full disclaimer, and terms & conditions. *** - ****" I explained that Choice Organics, as cited as the distributor on the individual bottles of O.P.M.S Black Liquid Kratom, lot [redacted], from sealed carton lot 2194, is a company that I helped create. I created the phone number and the email address associated with Choice Organics, per a request by Martian Sales. Once the phone number and email address was created, this information was provided back to Martian Sales. I am no longer involved with Choice Organics On 08/28/2024, I contacted Mr. Mark Reilly, of Martian Sales, regarding the different lot numbers per		
AFFIANT'S SIGNATURE AND TITLE		
FIRM'S NAME AND ADDRESS (Include ZIP Code)		
Jopen LLC d.b.a A1 Wholesale [redacted] (b)(4)		
Subscribed and sworn to before me at <u>Dallas, TX</u> , this <u>29</u> day of <u>August</u> , 20 <u>24</u> . _____ (Employee's Signature)		
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.		

AFFIDAVIT		SAMPLE NO.
STATE OF Texas	COUNTY OF Dallas	
Before me, <u>Brook Shea</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared <u>David E. Gabbay</u> in the county and state aforesaid, who, being duly sworn, deposes and says: a sealed container and the bottles it holds. Mr. Reilly explained to me that he is aware of the two different lot numbers, and that Martian Sales has the ability to trace both a carton and bottle. I believe that approximately <u> </u> of all incoming products are obtained from out of Texas and approximately <u> </u> of all products are shipped outside of Texas. <i>The affiant refused to sign the affidavit upon the direction of his legal counsel. The affiant declined to comment on the affidavit upon direction of his legal counsel</i> B. Shea CSO 08/29/2024		
AFFIANT'S SIGNATURE AND TITLE		
FIRM'S NAME AND ADDRESS (Include ZIP Code)		
Jopen LLC d.b.a A1 Wholesale 		
Subscribed and sworn to before me at <u>Dallas, TX</u> , (City and State)		
this <u>29</u> day of <u>August</u> , 20 <u>24</u> .		
_____ (Employee's Signature)		
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.		

EXHIBIT A-5

For Sample Number: 1268590

This is an accurate reproduction of the original electronic record as of 09/05/2024

Flag

Flag Remarks

Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Compliance	Official	24339904	Completed
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3032150939	08/28/2024	54KCE12	Manufacturer	21008	9
Compliance Num	Country of Origin				
	United States				
Related Smpl Num	Position Class	Sampling Organization	NDC Number	Permit Number	Storage Rqrmnt.
	INV	HAFW3			Ambient
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
No				O.P.M.S.	

Product Description

Liquid kratom extract packaged in (See "Remarks")

Product Label

See continuation.

Reason for Collection

Collected per Compliance/For-cause sample collection of kratom product during establishment inspection on 8/27-29/2024 under assignmet ID: 12383921 and Op ID: 12449807 to be analyzed for quantitation of 7-OH Mitragynine and Mitragynine.

MFG Codes

"2194"

Expiration Date

No Exp Date

Firm Legal Name

Jopen LLC, d.b.a A1 Wholesale

Address

4949 Beeman Ave Dallas, TX 75223-3012
US

Type of Firm

Dealer

Firm FEI

3011941572

FCE

Choice Organics

3680 Wilshire Blvd Ste P04-1084 Los
Angeles, CA 90010-2709 US

Shipper

3027395753

(b)(4)

(b)(4)

Shipper

(b)(4)

Nuza, LLC

3075 Chastain Meadows Pkwy Marietta, GA 30066-3354 US

Manufacturer

3032150939

Size of Lot

(b)(4) of liquid kratom
extract

Est. Value

\$

(b)(4)

Rcpt Type

FDA484

Carrier Name

Date Shipped

Description of Sample

Sample consists of (b)(4) of liquid kratom extract.

Method of Collection

See continuation.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"1268590 8/28/2024 SAV"

Collector's Identification on Seal

"1268590 9/3/2024 Sara A. Valenzuela, Investigator"

Sample Delivered To

UPS Store (b)(4), next
day air, (See "Remarks")

Date Delivered

09/03/2024

Orig C/R & Records To

HAFE3

Lab w/Split Sample

0

Lab

DENLHAF

Date: 09/05/2024

Page: 1 of 4

For Sample Number: 1268590

This is an accurate reproduction of the original electronic record as of 09/05/2024

Document Number	Document Date	Document Type	Document Remarks
1	09/03/2024	Other	Assignment sheet for assign ID: 12383921 and Op ID: 12449807 (2 pages)
2	08/27/2024	Other	FDA 482 - Notice of Inspection (3 pages)
3	08/29/2024	Other	FDA 484 - Receipt for Samples (2 pages)
4	08/28/2024	Other	Photos of product case labeling and FDA 484 - Receipt for Samples (8 pages)
5	08/13/2024	Bill of Lading	BOL for outgoing kratom product (2 pages)
6	08/29/2024	Affidavit	FDA 463a - Affidavit (4 pages)

Remarks

See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	No	Yes	Sara A Valenzuela

Name of Signer	Date & Time of Signature			Meaning
Sara A Valenzuela	09/05/2024	12:56 PM	ET	Collector
Sara A Valenzuela	09/05/2024	12:31 PM	ET	Collector
Sara A Valenzuela	09/05/2024	12:30 PM	ET	Collector
Sara A Valenzuela	09/05/2024	11:50 AM	ET	Collector

For Sample Number: 1268590

This is an accurate reproduction of the original electronic record as of 09/05/2024

Continuation:

Product Label

Front of case label reads in part "****O.P.M.S. BLACK LIQUID****".

Back of case label reads in part "****LOT - 2194".

Top of case label reads in part "****O.P.M.S. Distributed By: Choice Organics (213)-221-8049****Info@OPMSKratom.com
3680 Wilshire Blvd. Suite P04-111, Los Angeles, CA 90010".

UPC on back of case: 643375878777

Bottom of case label reads in part "****O.P.M.S. KRATOM EXTRACT".

Method of Collection

On 8/28/2024, during establishment inspection of Jopen, LLC d.b.a. A1 Wholesale, located at [REDACTED], I collected 1 case, lot #2194, containing [REDACTED] each of O.P.M.S. brand Black Liquid Katom Extract. The case was enclosed in clear, plastic wrap; I left the case packaging intact for sample collection, preparation, and shipment. The sample contains the 702(b) portion.

During the inspection, Mr. David E. Gabbay, Manager, opened one of the cases from the same lot (2194) and one of the individual bottles CSO Shea and I examined and collected had an inkjet of [REDACTED] printed on the bottom of the bottle. Mr. Gabbay was unaware if this was a separate lot number.

To ensure the uniformity of the same lot code, the sample collection focused on the outer packaging lot code, however, once the packaging is opened, it cannot be guaranteed that the bottle lot code will match the outer packaging lot code. The firm could not explain this discrepancy as they are not the manufacturer. Mr. Gabbay provided the names of two different firms as manufacturers, Martian Sales, Inc. (no location provided or located) and Nuza, LLC, located at 3075 Chastain Meadows Pkwy, Marietta, GA 30066.

A bill of lading (BOL) was collected for an outbound shipment of O.P.M.S. Black Liquid Kratom Extract by CSO Brook Shea. The BOL, [REDACTED] identifies [REDACTED] as the shipper, ship date of 8/13/2024, shipped to [REDACTED] located at [REDACTED]. There is no information contained within the BOL identifying the product, lot number, or amount. CSO Shea obtained an affidavit with information linking the BOL with the product, which Mr. Gabbay (the affiant) refused to sign on advice from council.

I transferred the sample via secure POV to my personal residence and stored it in a secure, locked room. On 8/29/2024, I transferred the sample via secure POV back to the firm in order to get clearer photographs of the case labeling. I transferred the sample back to my personal residence via secure POV and stored in a secure, locked room until I could prepare and ship the sample. At the close of the inspection on 8/29/2024, I issued a FDA 484 - Receipt for Samples to Mr. Gabbay, who provided the sample at no cost.

How Prepared

The sample was collected on 8/28/2024; however, I did not prepare or ship it until 9/3/2024. I was advised by DENLHAF that shipping after the Labor Day holiday would be ideal. The sample was held at my personal residence in a secure, locked room until preparation and shipment.

On 9/3/2024, I prepared the sample by placing a white, adhesive label bearing "1268590 8/28/2024 SAV" to the top, right of the product case. I then placed the sample inside of a large, unused whirl-pak bag, rolled the top of the bag down, and folded the

Date: 09/05/2024

Page: 3 of 4

For Sample Number: 1268590

This is an accurate reproduction of the original electronic record as of 09/05/2024

Continuation:

wire tabs over to secure. I placed an official seal, dated 9/3/2024 over the rolled portion of the whirl-pak bag and then I taped a completed FDA 525 over the seal using clear, plastic tape.

I lined the bottom of a cardboard box with bubble wrap, wrapped the sealed sample in bubble wrap and then placed it in the cardboard box. The sample was placed in the same box as sample #1268589. I placed more bubble wrap around and on top of the sample and then sealed the cardboard box using clear, packing tape. I applied clear, packing tape along all edges of the box and then affixed a UPS shipping label to the top of the box.

I transported the sample via secure POV to UPS Store [REDACTED] and shipped it utilizing next day air to DENLHAF to be analyzed for quantitation of 7 - OH mitragynine and mitragynine. The sample was collected, prepared, and shipped in conjunction with sample #1268589. I maintained chain of custody of the sample at all times.

Remarks

Lab is aware of additional analysis requested per the discussion with Chad Whitwell, HAFW3 CO and Kim Dutzek OC/DE CO.

The 702(b) portion is included in the sample.

I took a photo, of the original FDA 484 - Receipt for Samples due to the quality of the copy. Refer to document number 4.

The officially sealed original copy and unsealed working copy discs containing the photographs taken during the sample collection and inspection are filed with the unlabeled exhibits and attachments collected for the establishment inspection conducted 8/27-29/2024.

The sample was collected on 8/28/2024; however, due to the holiday weekend and on advice from DENLHAF, the sample was prepared and shipped on 9/3/2024

"Product Description" (continued): clear bottles with black, white, and green plastic wrap label and screw-on lid. Text on product bottle label in white, black, and green.

"Sample Delivered To" (continued): tracking [REDACTED]

Field Accomplishment And Compliance Tracking System (FACTS)

Assignment Sheet for: Sara A. Valenzuela

Assignment ID: 12383921**Operation ID:** 12449807**Type of Operation:** Domestic Sample Collection**Compliance Number:****Target Completion Date:** 09/30/2024**Requester Priority:** High**Scheduled Completion Date:****Organization Priority:****Subject:** Compliance/For-cause sample collection of kratom product**Background Information:****Requester's Remarks:****Work Remarks:****Investigator's Remarks:****Estimated Cost:****PAC(s):** 21008 DIETARY SUPPLEMENT SAMPLE COLLECTION AND ANALYSIS**Product:****Firm(s):****Consumer Complaints With Disposition
of 'Surveillance Information for next EI':****Requesting Organization:** HAFW3**Assignment POC Name:** Kristin N. Longfellow**Phone:** (214)253-5210**Fax:****Accomplishing Organization:** HAFW3**Performing Organization:** HAFW3-GRP5**Assignor:****Send samples to:****Other Assignee(s) on the Assignment within (HAFW3):**

=====

There are no other Assignees.

Field Accomplishment And Compliance Tracking System (FACTS)

Assignment Sheet for: Sara A. Valenzuela

District Use:

Firm POC Name:

There are no Points Of Contact

=====

Est Type

There are no Establishment Types

=====

Industry Code

There are no Industry Codes

=====

Registration Type

=====

Registration Date

=====

Profile Class

There are no Profile Classes

Last Covered Date Last Final Recommendation

There is no Last Covered Date

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT OFFICE ADDRESS & PHONE NO. 1701 Mann St Suite 1100 Dallas TX 75206 (214) 252 5200	
TO	2. NAME AND TITLE OF INDIVIDUAL David B. Gribby Manager		3. DATE 08/27/2019
	4. FIRM NAME Super LLC d.b.a. A1 Wholesale		5. HOUR 11:01 a.m.
	6. NUMBER AND STREET 4749 Roman Ave		
	7. CITY AND STATE & ZIP CODE Dallas TX 75223		8. PHONE NO. & AREA CODE 469 185-2662

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)]¹ and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264]²

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) (Food and Drug Administration Employee(s))	10. TYPE OR PRINT NAME(S) AND TITLE(S) (FDA Employee(s))
	Bruce Shea, CSO
	Sara A. Valenzuela, CSO

¹ Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information

described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this

(Continued on Reverse)

Act), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Sec. 704. (a)(2) The provisions of the third sentence of paragraph (1) shall not apply to (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice; (C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale; (D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Sec. 704. (a)(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records (A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or (B) required to be maintained under section 412.

Sec. 704(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, tobacco product, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

Sec. 704. (c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

Sec. 704. (d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m) (4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

²Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F – Licensing – Biological Products and Clinical Laboratories and* * * * *

Sec. 351(c) "Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation
(Continued on Page 3)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F - *****Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than \$50, to furnish manufacturers of such

products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

Sec. 360 B.(a) It shall be unlawful--

(1) ***

(2) ***

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS & PHONE NUMBER 1201 Main St., Ste 7200 Dallas, TX 75202 214-2533-5200	
2. NAME AND TITLE OF INDIVIDUAL David E. Galtberg, Manager		3. DATE 8/29/2024	4. SAMPLE NUMBER 1268589 + 12688909
5. FIRM NAME Topen, LLC 10-b. 123456789	6. FIRM'S DEA NUMBER N/A		
7. NUMBER AND STREET 44444 Berman Ave Ave.	8. CITY AND STATE (Include Zip Code) Dallas, TX 75223		
9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification) The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and/or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360ii(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form. (NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.) (b)(4) each of O.P.M.S. Black Liquid, sample # 1268589, Lot # 2194, (b)(4) each of O.P.M.S. Black Liquid, sample # 1268590, Lot # 2194 (b)(4) Total sample cost (b)(4) 			
10. SAMPLES WERE ☒ PROVIDED AT NO CHARGE ☐ PURCHASED ☐ BORROWED (To be returned)	11. AMOUNT RECEIVED FOR SAMPLE N/A ☐ CASH ☐ BILLED ☐ VOUCHER ☐ CREDIT CARD		12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge.)
13. COLLECTOR'S NAME (Print or Type) Sara A Valenzuela	14. COLLECTOR'S TITLE (Print or Type) Consumer Safety Officer	15. COLLECTOR'S SIGNATURE 	

Section 704 (c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] is quoted below:

"If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained."

Section 532(b) of The Federal Food, Drug and Cosmetic Act [21 U.S.C. 360 ii (b)] is quoted in part below:

"Section 532(b) In carrying out the purposes of subsection (a), the Secretary is authorized to-

- (1) ****
- (2) ****
- (3) ****

- (4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products"

21 Code of Federal Regulations 1307.02 is quoted below:

"1307.02 Application of State law and other Federal law.

Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such an act nor shall compliance with such be construed as compliance with other Federal or State laws unless expressly provided in such other laws."

Therefore, in the event any samples of controlled drugs are collected by FDA representatives in the enforcement of the Federal Food, Drug, and Cosmetic Act, the FDA representative shall issue a receipt for such samples on FDA Form 484, RECEIPT FOR SAMPLES, to the owner, operator, or agent in charge of the premises.

Report of analysis will be furnished only where samples meet the requirements of Section 704(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(d)] which is quoted below:

"Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge."

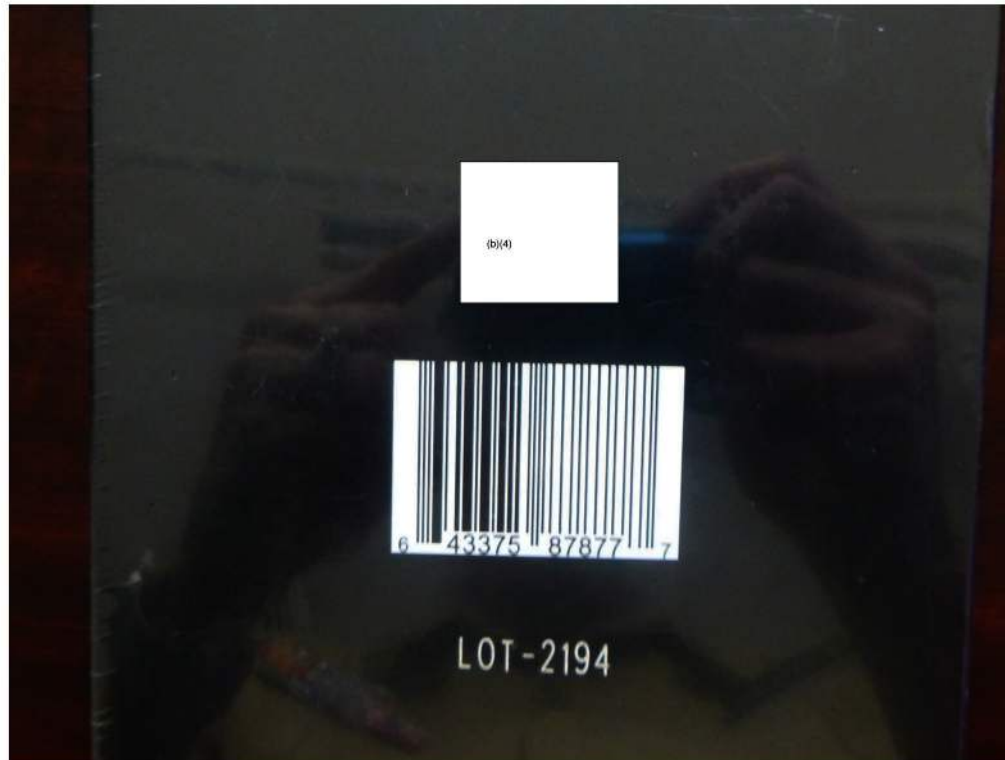








1268590 8/28/2024 SAV
Document 4, page 4 of 8



1268590 8/28/2024 SAV
Document 4, page 5 of 8





B

Page 19 of 25

Date:		BILL OF LADING		Page 1 of _____		
SHIP FROM						
Name: [Redacted]		Bill of Lading Number: [Redacted] [Redacted] [Redacted] 				
Address: [Redacted]						
City/State/Zip: Dallas TX 75223						
SID#: _____		FOB: ☐				
SHIP TO						
Name: [Redacted]		CARRIER NAME: [Redacted] (b)(4) Trailer number: Seal number(s): [Redacted] (b)(4)				
Address: [Redacted]						
City/State/Zip: Dallas TX 75223						
CID#: _____		SCAC: Pro number: Same as BOL number				
Location #: _____						
FOB: ☐						
THIRD PARTY FREIGHT CHARGES BILL TO:						
Name: _____		Freight Charge Terms: (<i>freight charges are prepaid unless marked otherwise</i>) Prepaid _____ Collect _____ 3rd Party _____ ☐ Master Bill of Lading: with attached underlying Bills of Lading (check box)				
Address: _____						
City/State/Zip: _____						
SPECIAL INSTRUCTIONS:						
CUSTOMER ORDER INFORMATION						
CUSTOMER ORDER NUMBER		# PKGS	WEIGHT	PALLETS/SKID (CIRCLE ONE)	ADDITIONAL SHIPPER INFO	
[Redacted]				Y N		
				Y N		
				Y N		
				Y N		
				Y N		
				Y N		
				Y N		
				Y N		
				Y N		
GRAND TOTAL						
CARRIER INFORMATION						
HANDLING UNIT		PACKAGE		COMMODITY DESCRIPTION	LTL ONLY	
QTY	TYPE	QTY	TYPE		NMFC #	CLASS
				Dry Grocery Products		
GRAND TOTAL						
RECEIVED BY: _____ STAMP DATE: _____						
Where the rate is dependent on value, shippers are required to state specifically in writing the agreed or declared value of the property as follows: The agreed or declared value of the property is specifically stated by the shipper to be not exceeding \$_____ or				COD Amount: \$_____		
				Fee Terms: Collect: ☐ Prepaid: ☐ Customer check acceptable: ☐		
NOTE: Liability Limitation for loss or damage in this shipment may be applicable. See 49 U.S.C. § 14706(c)(1)(A) and (B).						
RECEIVED, subject to individually determined rates or contracts that have been agreed upon in writing between the carrier and shipper, if applicable, otherwise to the rates, classifications and rules that have been established by the carrier and are available to the shipper, on request, and to all applicable state and federal regulations.				The carrier shall not make delivery of this shipment without payment of freight and all other lawful charges. Shipper Signature		
SHIPPER SIGNATURE / DATE		Trailer Loaded:		FREIGHT COUNTED:		
This is to certify that the above named materials are properly classified, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the DOT.		☐ By Shipper		☐ By Shipper		
		☐ By Driver		☐ By Driver/pallets said to contain		
				☐ By Driver/Pieces		
				CARRIER SIGNATURE / PICKUP DATE		
				Carrier acknowledges receipt of packages and required placards. Carrier certifies emergency response information has been made available and/or carrier has the DOT emergency response guidelines or equivalent documentation in its vehicle. Placard displayed where it is visible at most times, except as noted.		

STRAIGHT BILL OF LADING - SHORT FORM - ORIGINAL - NOT NEGOTIABLE

This form contains only the information necessary for the motor carrier to deliver, rate, and invoice the shipment described below.

Shipper: Ship Date 8/13/2024

(b)(4)	
Reference Number:	

(b)(4)

Consignee: Due Date 8/16/2024

(b)(4)	
Reference Number:	

Carrier:	
Pro#:	
Load#:	
BOL#:	

All Freight charges PPD/3rd party bill to:

(b)(4)

No. of Units & Container Type	BASIC DESCRIPTION		NMFC	CLASS	Total Weight
	Identification Number (UN or NA), Proper Shipping Name, Hazard Class, Packing Group	HAZ			
1 Pallet	detox supplements (42L 457 GPM)		57335-3	78	1050
*An X indicates hazardous material			Total weight: (subject to correction)		1050

Shipper Special Instructions:

PMT

Consignee Special Instructions:**Comments:****Overseas**

NOTICE: Freight moving under this Bill of Lading is subject to classifications and tariffs established by the carrier and are available to shipper upon request. This notice supersedes and negates any claimed oral or written contract, promise, representation, or understanding between parties, except to the extent of any written contract signed by both parties to the contract.

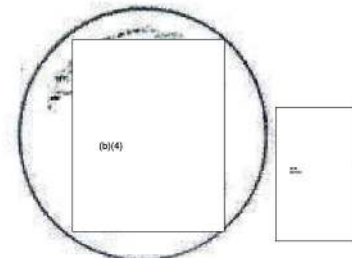
Any unauthorized alteration or use of this bill of lading or the tendering of this shipment to any carrier other than that designated by company, may VOID company's obligations to make any payments relating to this shipment and VOID all rate quotes. All shippers, consignors, consignees, freight forwarders or freight brokers are jointly and severally liable for the freight charges relating to this shipment.

CUSTOMER AGREES TO THE ORGANIZATION'S TERMS AND CONDITIONS, WHICH CAN BE FOUND AT WWW.FREIGHTWAYCENTER.COM.

The Shipper certifies that the above-named materials are properly classified, described, marked, labeled and packaged, and are in proper condition for transportation, according to the

Shipper Signature X _____ Date: 8/13 Trailer# _____
 Consignee Signature X _____ Date: _____ Seal# _____
 Driver Signature X _____ Date: _____ Seal# _____

Permanent post-office address of shipper:



AFFIDAVIT		SAMPLE NO.
STATE OF Texas	COUNTY OF Dallas	
Before me, Brook Shea, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared David E. Gabbay in the county and state aforesaid, who, being duly sworn, deposes and says:		
I, David E. Gabbay, am the Manager of [REDACTED] and Jopen LLC, doing business as A1 Wholesale, a distributor of various kratom products including O.P.M. S Black Liquid Kratom. A1 Wholesale contracts space from [REDACTED] and for the [REDACTED] to fulfill their order reception, holding, and shipment of products. The [REDACTED] is located at [REDACTED]. A1 Wholesale has offices located at 3200 Broadway, Suite 530, Garland, TX 75043. These offices do not store any products.		
My daily job tasks include managing contracts with customers and vendors. I have the ability to handle orders and product ordering. From approximately 2013 to 2016, I would contact Mr. Mark Reilly, of Martian Sales, located in Georgia, directly via a phone call to place orders for O.P.M.S. products. From approximately 2016 onward, O.P.M.S. products are [REDACTED] shipped to A1 Wholesale without the need of me placing orders. I only have [REDACTED] report, [REDACTED], an on-site A1 Wholesale and [REDACTED] Manager at the [REDACTED] location. I report directly to the Jopen, LLC trust. I have an unlimited budget authority to make changes to A1 Wholesale, and I have the duty and power to detect, prevent and correct food safety violations.		
A1 Wholesale receives orders of O.P.M.S. Black Liquid Kratom from Nuza, LLC. On 08/28/2024, I provided CSO Shea Bill of Lading# [REDACTED], shipped from Nuza, LLC, located at 3075 Chastain Meadows Pkwy, Marietta, GA 30066, on 09/07/2023, for O.P.M.S. Black Liquid Kratom lot # [REDACTED]. The lot number and description of products included are not listed on our incoming Bills of Lading (BOL). There is no [REDACTED] tracking system for A1 Wholesale that documents what lot numbers of O.P. M.S. Black Liquid Kratom are received, stored, and shipped from the [REDACTED] location. I have to contact Nuza, LLC in order to obtain incoming BOLs. The incoming BOLs I provided to CSO Shea were provided to me by Nuza, LLC. Nuza, LLC confirmed to me that Bill of Lading# [REDACTED], shipped from Nuza, LLC on 09/07/2023, is for the O.P.M.S. Black Liquid Kratom lot # [REDACTED]. The O.P. M.S. Black Liquid Kratom product is received in finished product form and A1 Wholesale does not manipulate the product further.		
On 08/29/2024, I provided CSO Shea BOL# [REDACTED] shipped from the A1 Wholesale [REDACTED] location on 10/18/2023 to a customer in Orland Park, IL 60462. The outgoing BOL I provided to CSO		
AFFIANT'S SIGNATURE AND TITLE		
FIRM'S NAME AND ADDRESS (Include Zip Code)		
Jopen LLC d.b.a A1 Wholesale [REDACTED]		
Subscribed and sworn to before me at Dallas, TX, this 29 day of August, 2024. (City and State)		
_____ (Employee's Signature)		
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.		

AFFIDAVIT		SAMPLE NO.
STATE OF Texas	COUNTY OF Dallas	
Before me, <u>Brook Shea</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared <u>David E. Gabbay</u> in the county and state aforesaid, who, being duly sworn, deposes and says: Shea was a A1 Wholesale shipping document. I contacted Nuza, LLC confirmed to me that Bill of Lading# <u>(b)(4)</u>, is for the O.P.M.S. Black Liquid Kratom lot # <u>-</u>. No amount or description of O.P.M.S. Black Liquid Kratom is on the BOL. A1 Wholesale receives orders for products, such as O.P.M.S. Black Liquid Kratom, from orders that are placed over the phone with Partynuts.com. To order from Partynuts.com a customer is to be vetted first, to ensure they are a business. This is done in a variety of ways including verifying tax ID's, the business' locations, etc. These sales are managed by <u>(b)(4)</u>, a contracted third party ordering system. A1 Wholesale's ordering software is then updated by <u>(b)(4)</u> with the order details. The orders are then passed to <u>(b)(4)</u> for their employees to pack and ship orders. Orders are packed and shipped with A1 Wholesale documentation. Orders are shipped via wholesale using third party trailers to customers. The current batch of O.P.M.S. Black Liquid Kratom in inventory at the <u>(b)(4)</u> location is lot# 2194. Shipments of the O.P.M.S Black Liquid Kratom come in sealed cartons of <u>(b)(4)</u> bottles. This lot, 2194, when opened, contained individual O.P.M.S. bottles containing the lot number <u>(b)(4)</u> with black ink on the bottom of the bottles. This lot, 2194, containing lot <u>-</u> bottles, was manufactured by Nuza, LLC. On 08/28/2024, I provided CSO Shea Bill of Lading# <u>(b)(4)</u>. The BOL states that both the ship from and ship to address as the <u>(b)(4)</u> location. Nuza, LLC began utilizing blind BOLs in 2023. that no longer state their name as the shipper. Nuza, LLC confirmed to me that Bill of Lading# <u>(b)(4)</u>, shipped from Nuza, LLC, is for the O.P.M.S. Black Liquid Kratom lot #2194. No date and amount is listed on the BOL. On 08/29/2024, I provided CSO Shea BOL# <u>(b)(4)</u> shipped from <u>(b)(4)</u> location on 08/13/2024 to a customer in <u>(b)(4)</u>. The outgoing BOL I provided to CSO Shea was a <u>(b)(4)</u> shipping document provided to A1 Wholesale. I contacted Nuza, LLC confirmed to me that Bill of Lading# <u>(b)(4)</u> is for the O.P.M.S. Black Liquid Kratom lot <u>-</u>. No amount or description of O.P.M.S. Black Liquid Kratom is on the BOL. <u>#2194 85 08/29/24</u> The label for the sealed carton of O.P.M.S. Black Liquid Kratom is in part, "***O.P.M.S. BLACK		
AFFIANT'S SIGNATURE AND TITLE		
FIRM'S NAME AND ADDRESS (include ZIP Code)		
Jopen LLC d.b.a A1 Wholesale <u>(b)(4)</u>		
Subscribed and sworn to before me at <u>Dallas, TX</u> (City and State)		
this <u>29</u> day of <u>August</u> , 20 <u>24</u> .		
(Employee's Signature)		
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.		

AFFIDAVIT		SAMPLE NO.
STATE OF Texas	COUNTY OF Dallas	
Before me, <u>Brook Shea</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared <u>David E. Gabbay</u> in the county and state aforesaid, who, being duly sworn, deposes and says: LIQUID*** WARNING: Do not use product before reading product inserts, labels, warnings, directions, disclaimers, and agreeing to the terms & conditions, and notices. Visit www.OPMSKratom.com for all updates including full disclaimer, and terms & conditions*** Usage size: 1/2 bottle - 4.4 ml, Usage per bottle: 2*** Mitragyna Speciosa (Kratom)- per 4.4ml per bottle*** Leaf extract total content: <108 mg ≤ 216 mg*** Mitragynine : ≤68 mg ≤135 mg*** 7-Hydroxymitragynine: ≤ 1 mg ≤ 1 mg*** Other Alkaloids: ≤40 mg ≤40 mg*** Other Ingredients: water, ethyl alcohol, propylene glycol, corn syrup, natural and artificial stabilization agents*** Distributed By: Choice Organics (213)-221-8049*** Info@OPMSKratom.com 3680 Wilshire Blvd. Ste P04-1111 Los Angeles, CA 90010*** LOT - 2194***. UPC: 643375878777 " The individual bottle labels are stored in cardboard containers, their label in part, "****O.P.M.S. BLACK LIQUID KRATOM EXTRACT 8.8ml*** WARNING: Do not use product before reading product insert, labels, warnings, directions, disclaimers, and agreeing to terms & conditions, and notices. Visit www.OPMSKratom.com for all updates including full disclaimer, and terms & conditions.*** Distributed By: Choice Organics (213)-221-8049 Info@OPMSKratom.com 2680 Wilshire Blvd. Suite P04-111, Los Angeles, CA 90010****. [redacted]****. UPC: 650075995130 The individual bottles, out of the cardboard containers, their label in part, "****O.P.M.S. BLACK LIQUID KRATOM EXTRACT*** 8.8ml***Warning: Do not use product before reading product insert, labels, warnings, directions, disclaimers, and agreeing to terms & conditions, and notices. Visit www.OPMSKratom.com for all updates including full disclaimer, and terms & conditions. *** [redacted] ****" I explained that Choice Organics, as cited as the distributor on the individual bottles of O.P.M.S Black Liquid Kratom, lot [redacted], from sealed carton lot 2194, is a company that I helped create. I created the phone number and the email address associated with Choice Organics, per a request by Martian Sales. Once the phone number and email address was created, this information was provided back to Martian Sales. I am no longer involved with Choice Organics On 08/28/2024, I contacted Mr. Mark Reilly, of Martian Sales, regarding the different lot numbers per		
AFFIANT'S SIGNATURE AND TITLE		
FIRM'S NAME AND ADDRESS (Include ZIP Code)		
Jopen LLC d.b.a A1 Wholesale [redacted]		
Subscribed and sworn to before me at <u>Dallas, TX</u> this <u>29</u> day of <u>August</u> , 20 <u>24</u> . (City and State) (Employee's Signature)		
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.		

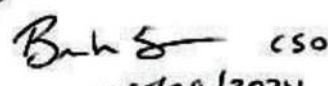
AFFIDAVIT		SAMPLE NO.
STATE OF Texas	COUNTY OF Dallas	
Before me, <u>Brook Shea</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared <u>David E. Gabbay</u> in the county and state aforesaid, who, being duly sworn, deposes and says: a sealed container and the bottles it holds. Mr. Reilly explained to me that he is aware of the two different lot numbers, and that Martian Sales has the ability to trace both a carton and bottle. I believe that approximately <u> </u> of all incoming products are obtained from out of Texas and approximately <u> </u> of all products are shipped outside of Texas. <i>The affiant refused to sign the affidavit upon the direction of his legal counsel. The affiant declined to comment on the affidavit upon direction of his legal counsel</i>  CSO 08/29/2024		
AFFIANT'S SIGNATURE AND TITLE		
FIRM'S NAME AND ADDRESS (Include ZIP Code)		
Jopen LLC d.b.a A1 Wholesale 4949 Beeman Ave, Dallas, TX 75223.		
Subscribed and sworn to before me at <u>Dallas, TX</u> , (City and State)		
this <u>29</u> day of <u>August</u> , 20 <u>24</u> .		
_____ (Employee's Signature)		
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.		

EXHIBIT A-6

Collection History Report

For Sample Number: 1268589

Flag	Flag Remarks				
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Version Num
	Domestic	Compliance	Official	24339901	2
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3032150939	08/28/2024	54KCE12	Manufacturer	21008	8
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	HAFW3			Ambient
Dealer is Consumer Crx/DEA Schedule Recall Num			Consumer Compl. Num	Brand Name	
No				O.P.M.S.	

Product Description

Liquid kratom extract packaged in (See "Remarks")

Product Label

See continuation.

Reason for Collection

Collected per Compliance/For-cause sample collection of kratom product during establishment inspection on 8/27-29/2024 under assignmet ID: 12383921 and Op ID: 12446135 to be analyzed for quantitation of 7-OH Mitragynine and Mitragynine.

MFG Codes

"2194"

Expiration Date

No Exp Date

Firm Legal Name

Jopen LLC, d.b.a A1 Wholesale

Address

4949 Beeman Ave Dallas TX 75223-3012
US

Type of Firm

Dealer

Firm FEI

3011941572

FCE

Nuza, LLC

3075 Chastain Meadows Pkwy Marietta GA
30066-3354 US

Manufacturer

3032150939

Choice Organics

3680 Wilshire Blvd Ste P04-1084 Los
Angeles CA 90010-2709 US

Shipper

3027395753

(b)(4)

(b)(4)

Shipper

(b)(4)

Size of Lot

(b)(4) of kratom extract

Est. Value

\$ (b)(4)

Rcpt Type

FDA484

Date Shipped & Doc. Ref.

Description of Sample

Sample consists of 1 case (50 units) of liquid kratom extract.

Method of Collection

See continuation.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"1268589 8/28/2024 SAV"

Collector's Identification on Seal

"1268589 9/3/2024 Sara A. Valenzuela, Investigator"

Sample Delivered To

UPS Store (b)(4),
next day air, (See "Remarks")

Date Delivered

09/03/2024

Orig C/R & Records To

HAFE3

Lab w/Split Sample

0

Lab

DENLHAF

Document Number

6

Document Date

08/29/2024

Document Type

Affidavit

Document Remarks

Affidavit (4 pages)

5

08/13/2024

Bill of Lading

BOL for outgoing kratom product (2 pages)

1

08/30/2024

Other

Assignment sheet for assign. ID: 12383921 and Op ID: 12446135 (2 pages)

Date: 01/23/2026

Page: 1 of 8

Collection History Report
For Sample Number: 1268589

2	08/27/2024	Other	FDA 482 - Notice of Inspection (3 pages)
3	08/29/2024	Other	FDA 484 - Receipt for Samples (2 pages)
4	08/28/2024	Other	Photos of product case labeling and FDA 484 - Receipt for Samples (8 pages)

Remarks

See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	No	Yes	Sara A Valenzuela
Name of Signer	Date & Time of Signature			Meaning
Sara A Valenzuela	09/05/2024 12:35 PM ET			Collector

Collection History Report

For Sample Number: 1268589

Continuation:

Version Num

2

Product Label

Front of case label reads in part "****O.P.M.S. BLACK LIQUID****".

Back of case label reads in part "****LOT - 2194".

Top of case label reads in part "****O.P.M.S. Distributed By: Choice Organics (213)-221-8049***Info@OPMSKratom.com 3680 Wilshire Blvd. Suite P04-111, Los Angeles, CA 90010".

UPC on back of case: 643375878777

Bottom of case label reads in part "****O.P.M.S. KRATOM EXTRACT".

Method of Collection

On 8/28/2024, during establishment inspection of Jopen, LLC d.b.a. A1 Wholesale, located at

(b)(4)

_____, I collected 1 case, lot #2194, containing _____ each of O.P.M.S. brand Black Liquid Kratom Extract. The case was enclosed in clear, plastic wrap; I left the case packaging intact for sample collection, preparation, and shipment. The sample contains the 702(b) portion.

During the inspection, Mr. David E. Gabbay, Manager, opened one of the cases from the same lot (2194) and one of the individual bottles CSO Shea and I examined and collected had an inkjet of _____ printed on the bottom of the bottle. Mr. Gabbay was unsure if this was a separate lot number.

To ensure the uniformity of the same lot code, the sample collection focused on the outer packaging lot code; however, once the packaging is opened, it cannot be guaranteed the bottle lot code will match the outer packaging lot code. The firm could not explain this discrepancy as they are not the manufacturer. Mr. Gabbay provided the names of two different firms as the manufacturer, Martian Sales, Inc. (no location provided or located) and Nuza, LLC, located at 3075 Chastain Meadows Pkwy, Marietta, GA 30066.

A bill of lading (BOL) was collected for an outbound shipment of O.P.M.S. Black Liquid Kratom Extract by CSO Brook Shea. The BOL, # _____, identifies _____ as the shipper, ship date of 8/13/2024, shipped to _____, located at _____. There is no information contained within the BOL identifying the product, lot number, or amount. CSO Shea obtained an affidavit with information linking the BOL with the product, which Mr. Gabbay (the affiant) refused to sign on advice from council.

I transferred the sample via secure POV to my personal residence and stored it in a secure, locked room. On 8/29/2024, I transferred the sample via secure POV back to the firm in order to get clearer photographs of the case labeling. I transferred the sample back to my personal residence via secure POV and stored in a secure, locked room until I could prepare and ship the sample. At the close of the inspection on 8/29/2024, I issued a FDA 484 - Receipt for Samples to Mr. Gabbay, who provided the sample at no cost.

How Prepared

The sample was collected on 8/28/2024; however, I did not prepare or ship it until 9/3/2024. I was advised by DENLHAF that shipping after the Labor Day holiday would be ideal. The sample was held at my personal residence in a secure, locked room until preparation and shipment.

On 9/3/2024, I prepared the sample by placing a white, adhesive label bearing "1268589 8/28/2024 SAV" to the top, right of the product case. I then placed the sample inside of a large, unused whirl-pak bag, rolled the top of the bag down, and folded the wire tabs over to secure. I placed an official seal, dated 9/3/2024 over the rolled portion of the whirl-pak bag and then I taped a completed FDA 525 over the seal using clear, plastic tape.

I lined the bottom of a cardboard box with bubble wrap, wrapped the sealed sample in bubble wrap and then placed it in the cardboard box. The sample was placed in the same box as sample #1268590. I placed more bubble wrap around and on top of

Date: 01/23/2026

Page: 3 of 8

Collection History Report

For Sample Number: 1268589

the sample and then sealed the cardboard box using clear, packing tape. I applied clear, packing tape along all edges of the box and then affixed a UPS shipping label to the top of the box.

I transported the sample via secure POV to UPS Store [REDACTED], and shipped it utilizing next day air to DENLHAF to be analyzed for quantitation of 7 - OH mitragynine and mitragynine. The sample was collected, prepared, and shipped in conjunction with sample #1268590. I maintained chain of custody of the sample at all times.

Remark

Lab is aware of additional analysis requested per the discussion with Chad Whitwell, HAFW3 CO and Kim Dutzek OC/DE CO.

The 702(b) portion is included in the sample.

I took a photo of the original FDA 484 - Receipt for Samples due to the quality of the copy. Refer to document number 4.

The officially sealed original copy and unsealed working copy discs containing the photographs taken during the sample collection and inspection are filed with the unlabeled exhibits and attachments collected for the establishment inspection conducted 8/27-29/2024.

The sample was collected on 8/28/2024; however, due to the holiday weekend and on advice from DENLHAF, the sample was prepared and shipped on 9/3/2024

"Product Description" (continued): clear bottles with black, white, and green plastic wrap label and screw-on lid. Text on product bottle label in white, black, and green.

"Sample Delivered To" (continued): tracking [REDACTED].

Collection History Report

For Sample Number: 1268589

Flag	Flag Remarks				
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Version Num
	Domestic	Compliance	Official	24339901	1
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3032150939	08/28/2024	54KCE12	Manufacturer	21008	8
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	HAFW3			Ambient
Dealer is Consumer Crx/DEA Schedule Recall Num			Consumer Compl. Num	Brand Name	
No				O.P.M.S.	

Product Description

Liquid kratom extract packaged in (See "Remarks")

Product Label

See continuation.

Reason for Collection

Collected per Compliance/For-cause sample collection of kratom product during establishment inspection on 8/27-29/2024 under assignmet ID: 12383921 and Op ID: 12446135 to be analyzed for quantitation of 7-OH Mitragynine and Mitragynine.

MFG Codes

"2194"

Expiration Date

No Exp Date

Firm Legal Name

Jopen LLC, d.b.a A1 Wholesale

Address

4949 Beeman Ave Dallas TX 75223-3012
US

Type of Firm

Dealer

Firm FEI

3011941572

FCE

Nuza, LLC

3075 Chastain Meadows Pkwy Marietta GA
30066-3354 US

Manufacturer

3032150939

Choice Organics

3680 Wilshire Blvd Ste P04-1084 Los
Angeles CA 90010-2709 US

Shipper

3027395753

(b)(4)

(b)(4)

Shipper

(b)(4)

Size of Lot

(b)(4) of kratom extract

Est. Value

\$ (b)(4)

Rcpt Type

FDA484

Date Shipped & Doc. Ref.

Description of Sample

Sample consists of (b)(4) of liquid kratom extract.

Method of Collection

See continuation.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"1268589 8/28/2024 SAV"

Collector's Identification on Seal

"1268589 9/3/2024 Sara A. Valenzuela, Investigator"

Sample Delivered To

UPS Store (b)(4),
next day air, (See "Remarks")

Date Delivered

09/03/2024

Orig C/R & Records To

HAFE3

Lab w/Split Sample

0

Lab

DENLHAF

Document Number

6

Document Date

08/29/2024

Document Type

Affidavit

Document Remarks

Affidavit (4 pages)

5

08/13/2024

Bill of Lading

BOL for outgoing kratom product (2 pages)

1

08/30/2024

Other

Assignment sheet for assign. ID: 12383921 and Op ID: 12446135 (2 pages)

Collection History Report
For Sample Number: 1268589

2	08/27/2024	Other	FDA 482 - Notice of Inspection (3 pages)
3	08/29/2024	Other	FDA 484 - Receipt for Samples (2 pages)
4	08/28/2024	Other	Photos of product case labeling and FDA 484 - Receipt for Samples (8 pages)

Remarks

See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	No	Yes	Sara A Valenzuela
Name of Signer			Date & Time of Signature	Meaning
Sara A Valenzuela			09/05/2024 11:27 AMET	Collector

Collection History Report

For Sample Number: 1268589

Continuation:

Version Num

1

Product Label

Front of case label reads in part "****O.P.M.S. BLACK LIQUID****".

Back of case label reads in part "****LOT - 2194".

Top of case label reads in part "****O.P.M.S. Distributed By: Choice Organics (213)-221-8049****Info@OPMSKratom.com 3680 Wilshire Blvd. Suite P04-111, Los Angeles, CA 90010".

UPC on back of case: 643375878777

Bottom of case label reads in part "****O.P.M.S. KRATOM EXTRACT".

Method of Collection

On 8/28/2024, during establishment inspection of Jopen, LLC d.b.a. A1 Wholesale, located at

(b)(4)

(b)(4), I collected 1 case, lot #2194, containing (b)(4) each of O.P.M.S. brand Black Liquid Kratom Extract. The case was enclosed in clear, plastic wrap; I left the case packaging intact for sample collection, preparation, and shipment. The sample contains the 702(b) portion.

During the inspection, Mr. David E. Gabbay, Manager, opened one of the cases from the same lot (2194) and one of the individual bottles CSO Shea and I examined and collected had an inkjet of (b)(4) printed on the bottom of the bottle. Mr. Gabbay was unsure if this was a separate lot number.

To ensure the uniformity of the same lot code, the sample collection focused on the outer packaging lot code; however, once the packaging is opened, it cannot be guaranteed the bottle lot code will match the outer packaging lot code. The firm could not explain this discrepancy as they are not the manufacturer. Mr. Gabbay provided the names of two different firms as the manufacturer, Martian Sales, Inc. (no location provided or located) and Nuza, LLC, located at 3075 Chastain Meadows Pkwy, Marietta, GA 30066.

A bill of lading (BOL) was collected for an outbound shipment of O.P.M.S. Black Liquid Kratom Extract by CSO Brook Shea. The BOL, # (b)(4), identifies (b)(4) as the shipper, ship date of 8/13/2024, shipped to (b)(4), located at (b)(4). There is no information contained within the BOL identifying the product, lot number, or amount. CSO Shea obtained an affidavit with information linking the BOL with the product, which Mr. Gabbay (the affiant) refused to sign on advice from council.

I transferred the sample via secure POV to my personal residence and stored it in a secure, locked room. On 8/29/2024, I transferred the sample via secure POV back to the firm in order to get clearer photographs of the case labeling. I transferred the sample back to my personal residence via secure POV and stored in a secure, locked room until I could prepare and ship the sample. At the close of the inspection on 8/29/2024, I issued a FDA 484 - Receipt for Samples to Mr. Gabbay, who provided the sample at no cost.

How Prepared

The sample was collected on 8/28/2024; however, I did not prepare or ship it until 9/3/2024. I was advised by DENLHAF that shipping after the Labor Day holiday would be ideal. The sample was held at my personal residence in a secure, locked room until preparation and shipment.

On 9/3/2024, I prepared the sample by placing a white, adhesive label bearing "1268589 8/28/2024 SAV" to the top, right of the product case. I then placed the sample inside of a large, unused whirl-pak bag, rolled the top of the bag down, and folded the wire tabs over to secure. I placed an official seal, dated 9/3/2024 over the rolled portion of the whirl-pak bag and then I taped a completed FDA 525 over the seal using clear, plastic tape.

I lined the bottom of a cardboard box with bubble wrap, wrapped the sealed sample in bubble wrap and then placed it in the cardboard box. The sample was placed in the same box as sample #1268590. I placed more bubble wrap around and on top of

Date: 01/23/2026

Page: 7 of 8

Collection History Report

For Sample Number: 1268589

the sample and then sealed the cardboard box using clear, packing tape. I applied clear, packing tape along all edges of the box and then affixed a UPS shipping label to the top of the box.

I transported the sample via secure POV to UPS Store [REDACTED], and shipped it utilizing next day air to DENLHAF to be analyzed for quantitation of 7 - OH mitragynine and mitragynine. The sample was collected, prepared, and shipped in conjunction with sample #1268590. I maintained chain of custody of the sample at all times.

Remark

The 702(b) portion is included in the sample.

I took a photo of the original FDA 484 - Receipt for Samples due to the quality of the copy. Refer to document number 4.

The officially sealed original copy and unsealed working copy discs containing the photographs taken during the sample collection and inspection are filed with the unlabeled exhibits and attachments collected for the establishment inspection conducted 8/27-29/2024.

The sample was collected on 8/28/2024; however, due to the holiday weekend and on advice from DENLHAF, the sample was prepared and shipped on 9/3/2024

"Product Description" (continued): clear bottles with black, white, and green plastic wrap label and screw-on lid. Text on product bottle label in white, black, and green.

"Sample Delivered To" (continued): tracking [REDACTED].