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SUMMARY

Assessment	
Operation ID and Name	234201: FY24, Tailwind Nutrition

Summary Data	
This is a comprehensive report.	
Inspection Basis	Surveillance

Summary

This unannounced routine, comprehensive, non-high-risk establishment inspection of Tailwind Nutrition, a powdered sports drink mix manufacturer, located in Durango, CO, was conducted under Compliance Program 7303.040 (*Preventative Controls and Sanitary Human Food Operations; 10/15/2020)* and covered 21 CFR 117(*Current Good Manufacturing Practice (cGMP), Hazard Analysis, and Risk-Based Preventive Controls for Human Food)* subparts A, B, and F, with a broad assessment of subparts C and G. This inspection was conducted per the HAFW4 FY'24 workplan under eNSpect Operation ID: 234201

Tailwind Nutrition, located in Durango, Colorado, is a wholesale manufacturer of powdered sports drink mix; a Ready-To-Eat (RTE) product with the addition of water. No further processing is required prior to consumption. Product is a conventional food item, not a dietary supplement.

On arrival to the firm on 05/14/2024, I presented my credentials, and issued Form FDA-482 Notice of Inspection, to Monika (NMI) Reck-Glenn, Quality Assurance (QA) Manager. She stated she is the Most Responsible Individual on site in the absence of Mr. Brer C. Bales, Director of Operations.

This is the firm's initial inspection from the Food & Drug Administration (FDA). The current inspection included coverage of the firms receiving, production, storage, and shipping, as well as sanitation, employee training, consumer complaints, recall procedures, and pest control. I observed the firms receiving, production, sanitation, and storage procedures.

At the close-out meeting on 05/15/2024 with Monika (NMI) Reck-Glenn, Quality Assurance Manager, no Form FDA-483 Inspectional Observations was issued and there were no discussion items.

No refusals were encountered, no samples collected and no consumer complaints or recalls reported in Field Accomplishments and Compliance Tracking System (FACTS) or Recall Enterprise System (RES) awaiting FDA disposition.

Program Assignment Codes Covered

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

Consumer Complaints Review
Ms. Reck-Glenn stated that the firm does have a complaints procedure. Complaints are received through the firm's website, email and phone call. Ms. Reck-Glenn stated that every complaint receives an investigation and follow-up as necessary. She stated they have not had any consumer complaints of adverse event, illness, injury or death. No consumer complaints recorded in FACTS for FDA disposition. They maintain a complaints log for all their consumer complaints. I reviewed their complaints records from 06/25/2019 through 04/24/2024. Their records show one complaint related to food safety they received on 12/18/2023 regarding a foreign object in their product. She went on to state this is the only food safety complaint they have ever received. Their root-cause analysis of the complaint concluded that it was piece of the lid from large blue bins they use to store the bulk blend. She stated in response to this occurrence they added a visual inspection of the blue bin lids during sanitation.

ADMINISTRATIVE DATA

Administrative Data	
Firm	Tailwind Nutrition
Physical Address	
Address Line 1	325 County Road 309a
City / State / ZIP	Durango, CO 81303-8247
Phone	970-903-7645
Mailing Address	
Address Line 1	325 County Road 309a
City / State / ZIP	Durango, CO 81303-8247
Email Address	supportcrew@tailwindnutrition.com
Website	https://tailwindnutrition.com/
Inspection Date(s)	5/14/2024, 5/15/2024

FDA Inspection Participants
Participant Name and Title
Samantha Rafferty, 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**
5/14/2024	Monika Reck-Glenn, Quality Assurance Manager

FDA Credentials Were Displayed to the Following Person(s)	
Person's Name and Title	Monika (NMI) Reck-Glenn, Quality Assurance (QA) Manager

FDA Credentials Were Displayed to the Following Person(s)	
Person's Name and Title	Brer C. Bales, Director of Operations

FMD-145 Recipient and Industry Portal Representative/Most Responsible Corporate Official*		
IPR/FMD Person		
Person's Name and Title	Jeffrey Vierling, Owner	Industry Portal Representative and FMD-145 Recipient
Email Address	jeff@tailwindnutrition.com	
Mailing Address	The same as the firm's mailing address.	
Phone Number	970-903-7645	
*If a corporation		

HISTORY

Food Firm Registration Status	Current	
Hours of Operation	Monday through Friday from 6:00 AM to 4:30 PM; all production ceases at 4:00 PM daily.	
New or Current Firm Legal Name	Tailwind Nutrition, Inc.	
Legal Status	Inc	
State of Incorporation	CO	
Year of Incorporation	2018	
Additional Information	Tailwind Nutrition, Inc. was formed by Mr. Jeffrey Vierling, Owner, in 2011 and started manufacturing powdered sports drink mix in 2015. The company is owned 50/50 by Mr. Jeffrey Vierling and Mrs. Jennifer Vierling. The company corporate office is located at 1309 E. 3rd Ave. Unit 207, Durango, CO 81301. Ms. Reck-Glenn stated that they moved into their current 15,000 sq.ft. facility in November 2022. She stated that they currently have 30 full-time employees. Firm is a Category 9 for their Gross Annual Sales (GAS). Firm is currently in “active” status for FDA Food Facility Registration (FFR) as of 11/15/2022 as required by the Food Drug and Cosmetic (FD&C) Act. Firm has no reported consumer complaints or recalls in Field Accomplishments and Compliance Tracking System (FACTS) or Recall Enterprise System (RES) for FDA disposition.	

INTERSTATE (I.S.) COMMERCE

Description of Interstate	

Commerce	Ms. Reck-Glenn stated the firm is approximately 75% wholesale. She stated that they receive 90% of their raw materials from outside of the state of Colorado. They distribute 90% of their product finished product outside the state of Colorado. Firms top three out-of-state suppliers are Top Secret located in Canada, Pure Salt in Phoenix, AZ, and Kinds & Flavors in California. Firm distributes their products nationwide with their top three customers being REI, The Feed, and Amazon. Ms. Reck-Glenn provided and verified the following document **[Exhibit #1 – Incoming Raw Material Interstate Documents Packet]** original copies showing incoming interstate movement of 50 bags (50lb each) of the raw material Citric Acid, Lot #30600296, from American International Foods American Select distribution center, located at 735-57 Myrtle Street, Elizabeth, NJ 07206, on 04/19/2024, via SAIA Transport, to Tailwind Nutrition, located at 325 CR 309 A, Durango, CO 81301. 1. Tailwind Nutrition's "Purchase Order" #PO1383 shows the purchase of 50 - 50lb bags of Citric Acid on 04/15/2024 from American International Foods to be shipped to Tailwind Nutrition warehouse located at 325 CR 309 A, Durango, CO 81301. 2. American Select Distributions "Straight Bill of Lading" BOL#S0143763, PO#1383, shows the interstate movement of 50 - 50lb bags of Citric Acid, Lot#30600296, from American International Foods to American Select distribution center, located at 735-57 Myrtle Street, Elizabeth, NJ 07206, on 04/19/2024, via SAIA Transport, to Tailwind Nutrition, located at 325 CR 309 A, Durango, CO 81301.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Description of Jurisdiction	Tailwind Nutrition, Inc., located in Durango, Colorado, is a wholesale ambient manufacturer of powdered sports drink mix; a Ready-To-Eat (RTE) product with the addition of water. No further processing is required prior to consumption. Product is a conventional food item, not a dietary supplement. They currently manufacture and distribute the following powdered sports drink mix: 1. Endurance Fuel (uncaffeinated or caffeinated) **[Exhibit #2 - Product Labeling]** 2. Recovery Mix (uncaffeinated or caffeinated) Ms. Reck-Glenn stated they are in the final stages of their new product line

	formulation Rapid Hydration. They are projected to be launching their new product in Summer 2024. Firm does not own any of their own carriers or delivery trucks, they use UPS, FedEx and USPS for all their nationwide orders. They will schedule a freight carrier for international orders. Ms. Reck-Glenn said their product promotion is primarily through their website and social medias. She stated they also promote their products at sports events.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	Monika (NMI) Reck-Glenn, Quality Assurance (QA) Manager
Roles and Authorities	Ms. Reck-Glenn stated she has been with the company for three years and was hired into her current position. She stated she reports directly to Mr. Brer Bales, Director of Operations, and stated she is the most responsible individual on site in his absence. She stated that her key roles and responsibilities are overall food safety and quality assurance, quality control, research and development, raw material procurement, and food safety training for employees. She stated that she has 15 years of food safety and operations experience, has a degree in microbiology and has completed multiple food safety trainings throughout that time. She stated she is the firms Preventive Controls Qualified Individual. Though she is not PCQI certified via a course, she stated she has the knowledge, training and experience in the development and application of risk-based preventive controls equivalent to that received under a standardized curriculum. She has the power to hire/fire personnel. She has the duty, power, responsibility, and authority to prevent, detect, and correct violations. She was present for entirety of inspection and provided me with requested documents/records for review.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection
Person #2	
Person's Name and Title	Brer C. Bales, Director of Operations
Roles and Authorities	Mr. Bales stated he started at the company in 2016 and has been in his current position since 2020. He stated he is the most responsible individual of the physical plant and its daily operations. He reports directly to Mr. Jeffrey Vierling, Owner. His key roles and responsibilities are overall firm operations, employee safety, corporate communications, overseeing incoming and outgoing inventory, food safety and customer service. He stated that in his absence, Ms. Reck-Glenn is the most responsible individual on site and that she is the most knowledgeable individual for all food safety operations, formulation, and

	production information. He has the duty, power, responsibility, and authority to prevent, detect, and correct violations. He has the power to hire/fire personnel. Mr. Bales was present a short time during the inspection on 05/15/2024, and was not present for the initiation or close out of the inspection.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed
Person #3	
Person's Name and Title	Jeffrey Vierling, Owner
Roles and Authorities	Mr. Jeffrey Vierling founded the company in 2011 and has held his current position since. Mr. Vierling was not present for the inspection and is based out of their corporate office located at 309 E. 3rd Ave. Unit 207, Durango, CO 81301. Ms. Reck-Glenn and Mr. Bales stated that he is the top management official (TMO), FMD-145, and all official correspondence should be addressed to his attention. They stated that he holds chain of command and has the ultimate duty, power, and responsibility to prevent, detect and correct violations. Ms. Reck-Glenn stated that his key roles and responsibilities are overall business logistics and operations, financial logistics, and human-resources. He has the power to hire/fire personnel.
The following are applicable to this person	Industry Portal Representative, FMD 145 Recipient
Email Address	jeff@tailwindnutrition.com
Mailing Address	The same as the firm's mailing address.
Phone Number	970-903-7645

FIRM'S TRAINING PROGRAM

Ms. Reck-Glenn stated that the firm does have a written SOP training program titled "Production Employee Health Standards and Food Contamination Prevention Training". These trainings cover handwashing and personnel practices, good manufacturing practices, and food safety. Training is conducted when the new employee begins their employment. Annual refresher trainings are conducted in a group. This is a requirement for all employees. Ms. Reck-Glenn stated that they are currently working on utilizing an online program for all of their training and record storage.

Ms. Reck-Glenn stated she is the firms Preventive Controls Qualified Individual (PCQI) and is responsible for employee training (see Individual Responsibility).

I reviewed the initial new hire training records for the following production employees: Zachariah Wood - completed on 05/10/2024
Ryan Weber - completed on 01/02/2024
Lara Gauge - completed on 04/12/2024
Jacob Christer - completed on 11/17/2022

MANUFACTURING/DESIGN OPERATIONS

Process Flow, Operations, and Product Coverage

Manu/Design:

Tailwind Nutrition, Inc. is a manufacturer of powdered sports drink mix. Their product is a ready-to-eat product that is made to be drinkable with the addition of water; no further processing is required. They produce two product lines: "Endurance Fuel" a sugar (dextrose) and electrolyte blend and "Recovery Drink" a high protein and electrolyte blend. Both products have caffeinated and caffeine free options. They are bringing their third product line "Rapid Hydration" to market Summer 2024; this blend is like their "Endurance Fuel" with less sugar content and is caffeine free.

Ms. Reck-Glenn stated the firm has a written Food Safety Plan (FSP). They are currently in the process of reanalysis and updating it to reflect their newest product they are bringing to market "Rapid Hydration."

Firm is currently using the electronic Administrative Management System (AMS) NetSuite for all product inventory tracking from receiving raw ingredients through shipping of their finished product. She stated they are in the process of replacing NetSuite with implementing the use of the Quality Management System (QMS) MasterControl system. MasterControl will enable them to have all their electronic records in one place, including but not limited to, inventory, standard operating procedures (SOP), production records, raw ingredient CoAs, formulations, test result records, product information, supplier information and production scheduling. She stated this system will be in been in place by the end of Summer 2024.

Firm produces one product line bulk base blend at a time and takes approximately one to two weeks to go through.

General Process Flow for all Product Lines:

Receive and store raw ingredients → Transfer of selected raw ingredients to white holding bins → Quality Control sampling at in-house laboratory for raw ingredients received → Sifting, weighing of selected raw ingredients → Mixing of selected raw ingredients → Transfer of finished blend to large blue storage bins → Pulling finished product quality control sample, retain sample and taste testing sample → Weighing and packaging of finished products: multi serving pouches or single serving stickpacks and sachets → CCP#1 Metal detection for pouches, stickpacks and sachets → Inkjet printing manufacturing code onto finished packaged products → Case packing and palletizing → Final quality control visual check and release to storage warehouse awaiting distribution → Shipping of finished products

During the inspection, I observed the production and packaging of their finished product Endurance Fuel Berry flavor multi serving pouch.

Receiving:

At receiving of the raw ingredients, they will check that the lot information and expiration date matches their order. All incoming raw ingredients are visually checked for damages or signs of contamination and their receiving log is completed. They check the truck to visually confirm cleanliness. Raw materials are

Process Flow, Operations, and Product Coverage

purchased from approved suppliers and all incoming raw materials require a Certificate of Analysis (CoA). Ms. Reck-Glenn stated she conducts an on-site audit for their approved suppliers within the first year of use. All receiving documents are filed and maintained, and the raw ingredients lot information is entered into NetSuite. If the incoming raw ingredients does not match the order, they will notify the supplier. Each supplier has an electronic file with all their compliance documents. The raw ingredients will be separated and quarantined until they determine how to proceed with it. The raw ingredients will be labeled with a "QC HOLD" sign.

Process Flow: Endurance Fuel Berry Flavor Multi-Service Pouch

Bulk Blend:

Production employee pulls the raw materials required for production of the unflavored base blend following the printed batch production sheet. This batch production record will stay with the base blend throughout remainder of production. The batch production sheet states required weights for each raw material and the specific lot to pull from. The raw materials are pulled from the designated area in the storage warehouse and moved to the production room via a forklift to begin production. Firm produces approximately 2000 kg of base blend at one time.

Raw ingredients are each weighed out to approximately 50 kg into clean white plastic holding bins with lids and labeled with the raw ingredient and lot code. All raw ingredients are sampled for quality control and analyzed at their in-house laboratory.

The white holding bins are stored on designated shelving next to the weigh station for easy access during production. Production employee will confirm the raw material and lot code with the batch production record. Then weigh out the required weights of raw material and record actual values on batch production record. The weighed out raw materials are then poured into the hopper of the gravity fed sifter and air cyclone piped to the Munson mixer. The Munson mixer is mounted on a scale to verify weight. Once all raw materials are added the base blend is then mixed in the Munson mixer for 10 minutes and poured into the large blue storage bins, up to 1000 kg each. If a flavored blend, the specified product flavoring is added to the base blend and mixed for 10 minutes in the Munson mixer. The completed batch production record is attached via clipboard to the correlating large blue storage bin with a lid until packaging.

Ms. Reck-Glenn will pull a quality control sample, a retain sample and a sample for taste testing from the finished product blue storage bin. Product will not be packaged until it is released from quality control.

Finished Product/Packaging:

Once the finished product has been released by quality control it is ready for packaging.

Production employee will transfer the finished product large blue storage bin to the multiservice pouch packaging line. Using a large tube, the finished product blend is vacuumed up into the packaging line filler hopper. The finished product blend is meter dosed into the multiservice pouch to the set weight. The pouch is conveyed down the line to the packaging line employee that will place a compostable serving scoop into the pouch and do a single bounce of the pouch to settle the powder. The pouch is then conveyed to the Doughboy heat sealer and inkjet printed with the lot code and best by date.

Process Flow, Operations, and Product Coverage

They also manufacture single serving stickpacks and sachets on their second packaging line. They have a custom machine made by Viking Masek which does the foil packaging for the stick and sachet packages. The finished product blend is poured into the filler hopper and meter dosed into the single serving foil packages. The machine will inkjet print the lot code and best by date onto the finished stickpacks and sachets. The stickpacks and sachets are then conveyed through the metal detector and into a bin. Packaging employee will then hand pack the cases, label, and palletize them.

Ms. Reck-Glenn stated that these are the only two lines for packaging that they have.

All large blue storage bins with finished product are sealed for overnight storage when they are in the middle of a production run of a specific product line. They will close the bins and store them overnight and continue with their operations the following day.

All finished sealed packages go through the metal detector, this is the firms only process Critical Control Point (CCP) for foreign material hazards. Firm has two metal detectors with one on each packaging line. The firm conducts accuracy checks on the metal detectors every four hours during production and record in their metal detection log. I reviewed the internal log from November 21, 2022, through May 14, 2024; no deviations reported. Ms. Reck-Glenn stated the metal detectors are calibrated biannually.

Finished product is then placed into cardboard cases, palletized, labeled with a stick-on pallet label and moved to their ambient warehouse for storage until shipping. Finished product quality control (QC) testing must be completed before the finished product is released into commerce; product is labeled with a QC release sticker.

Shipping:

When a product is set to be shipped, the shipping employee will print the shipping labels and using them as a packing list they pull the product from the storage warehouse. Shipping employee will scan the shipping label then the selected product, if product doesn't match scanner will alert the shipping employee. Picked product will be palletized for freight shipping. The most common freight carriers they use are Old Dominion and Schneider. Otherwise, they handpick for smaller shipments that go through FedEx, USPS and UPS.

Sanitation:

Ms. Reck-Glenn stated that they do a wet clean in between production runs. The firm uses Vigarox sanitizer, a peracetic acid cleaning sanitizer, concentration range of 80 to 500 ppm. Production employee pours warm water into the mixer, drained, then Vigarox sanitizer is poured into the mixer and ran for one minute. She stated they use Simple Green 5+ a quaternary ammonia sanitizing agent on all the external parts of machinery. All removable parts and all totes are washed and sanitized with Simple Green 5+ in their three-part sink.

They conduct dry cleaning on all equipment using designated vacuums at the end of every production day. All the floors are vacuumed, and all counters are wiped down with Simple Green 5+ in a white bucket with a clean rag. Dirty white buckets are stacked by the three-part sink and cleaned every two weeks or as often

Process Flow, Operations, and Product Coverage

as needed. She stated they additionally contract a third-party cleaning company to clean their floors, restrooms, and breakroom.

They clean and sanitize the large blue storage bins by hosing them down with water, then pour Simple Green 5+ sanitizer into them.

Ms. Reck-Glenn stated the firm follows a chemical sanitizer monitoring procedure for their Simple Green 5+ concentration with a range of 200 to 400 ppm. I reviewed the documents from November 30, 2022 through May 14, 2024. I observed an out-of-range concentration of 500 ppm reported on November 3, 2023. Ms. Reck-Glenn stated they conducted retraining with this specific production employee multiple times with no change and the production employee was let go. She stated they have a team meeting following this incident to discuss the importance of have the right sanitizer concentration and conducted a retraining for the employees. I observed the team meeting notes and employee attendance on November 3, 2023.

Ms. Reck-Glenn stated they have a Hygiena ATP handheld device on with an estimated arrival time of mid-May 2024. Ms. Reck-Glenn stated that once they receive their new Hygiena ATP device they will start conducting post sanitation ATP swab testing on their equipment. Additionally, they will be testing for the presence of *E. coli* and *Salmonella spp*. with the device.

Product Testing:

Ms. Reck-Glenn stated that they conduct testing in and out of house, and that she is responsible for testing. For out of house testing, they use Eurofins Laboratory located at 2200 house Rittenhouse St. Suite 150 Des Moines, IA 50321; phone number (515) 265-1461.

Ms. Reck-Glenn stated that they conduct finished product sampling once weekly for in-house pH and moisture content testing. She stated they collect one serving worth of finished product for their quality control testing they send out to a Eurofins Laboratory. Additionally, they collect two scoops of finished product for their retain sample and an additional scoop for taste testing.

Finished product pH testing conducted in-house for each retain sample collected. Ms. Reck-Glenn stated they will also do TDS testing if the pH is off or if a customer requests it specifically.

She stated they send out a sample (250 grams) of finished product annually for each product line to be analyzed for identity, strength, composition, water activity (range <0.5 at 25 degrees Celsius), moisture content (range <10%), nutritional breakdown, pathogens (S*almonella spp., E. coli, Staph aureus*, and total Coliform), heavy metals (Arsenic, Mercury, Lead and Cadmium), mold and yeast (range <10 cfu/g) and anaerobic place count (APC) (range <30 cfu/g).

I reviewed their most recent annual testing results for their Endurance Fuel Caffeinated product line, collected December 4, 2023 for pathogen testing, identity, strength, composition, nutritional breakdown, heavy metals. Results were unremarkable, no deviations observed. Recovery Mix was last analyzed on June 23, 2021. Ms. Reck-Glenn stated that they are currently reformulating the Recovery Mix and will conduct a new analysis of the finished product upon completion of that reformulation. Individual flavors were last sent out for analysis 2021.

Process Flow, Operations, and Product Coverage
Product Rework: Ms. Reck-Glenn stated that they do not currently have a written procedure for product rework, but she stated that they have only ever had to rework one time for a product. They had to stop a production run because the weights were off when they took it to the lab for testing. They determined that it was missing the potassium chloride in the formulation, she stated that they were able to add it in and we were able to still package for shipping. This is the only time that they've ever done rework to a product otherwise no they do not have any rework procedures. **Pest Control:** Ms. Reck-Glenn stated that they use Orkin for their pest control service. Orkin is on site at least once monthly. I reviewed the firms Orkin records from June 9, 2023, through May 15, 2024. Reports of activity on the external traps of bait eating and dead insects. No pest activity reported internally. During the current inspection, I observed no signs of pest activity or routes of contamination. Ms. Reck-Glenn stated that all employees are to notify her with any sightings of pest activity. She stated that they are going to implement a new pest sighting log that will be posted for all employees to record what they observe. **Waste Disposal:** Firm uses GFL Environmental for their waste disposal, they come once weekly for pick up. I observed the area around the dumpsters to be free of debris buildup.

Food Safety Plan (Limited Scope)		
Basic Food Information		
Product Name	"Endurance Fuel" Berry Flavored	
Product Code	41 Y G Y 99	Dietary Conventional Foods, N.E.C.
Product Description with Packaging	Endurance Fuel ready-to-mix powdered drink in a blue plastic sealed bag	
Intended Use	Powdered drink mix intended for high endurance athletes, such as but not limited to, ultra-marathon runners	

MANUFACTURING CODES

Ms. Reck-Glenn explained that they use the date of blending of the bulk base mix for their manufacturing coding system. She stated for each batch run sequentially completed with the bulk blend they will add a letter at the end of the lot code.

Example: Endurance Fuel Berry Finished Product Manu Code **"24050902 - D"**
Bulk Blend - YYMMDD + Flavor Code – XX + Batch Run – D

Shelf Life per product:
Endurance Fuel and Rapid Hydration → three years

Recovery Mix → two years

RECALL PROCEDURES

Ms. Reck-Glenn stated the firm does have a written recall procedure titled "Product Recall Program". She stated she is the firms recall coordinator. If a recall notice is received, or if they initiate a voluntary recall, all product information is collected, assessed and product disposition is determined, and all information is disseminated to all necessary parties. They conduct mock recalls annually. She stated they are currently working on setting up the new online master control system to make it easier for sorting information and locating records faster. She stated they have never had a recall, and there are no recalls reported in RES for FDA disposition.

REFUSALS

Inspection Refusals
No refusal

GENERAL DISCUSSION WITH MANAGEMENT

At the close-out meeting on 05/15/2024 with Ms. Monika Reck-Glenn, no Form FDA-483 Inspectional Observations was issued, though there was We reviewed and discussed Title 21 CFR Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Control for Human Food. Specifically, we reviewed Subpart A - General Provisions Part 117.4 Qualifications of individuals who manufacture, process, pack, or hold food, all of Subpart B - Current Good Manufacturing Practice, Subpart C – Hazard Analysis and Risk-Based Preventive Controls, Subpart F - Requirements Applying to Records That Must Be Established and Maintained and Subpart G - Supply Chain Program.

SAMPLES COLLECTED

No samples were collected.

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
1	Exhibit #1 - Incoming Raw Material Interstate Documents Packet - Tailwind Nutrition, Inc. - 2 pages	2
2	Exhibit #2 - Product Labeling - Endurance Fuel Berry flavor - Tailwind Nutrition, Inc. - 2 pages	2
3	Exhibit #3 - Food Safety Plan Table of Contents - Tailwind Nutrition, Inc. - 2 pages	2

ATTACHMENTS

Attachments		
Attachment Number	**Description**	**Number of Pages**
1	Attachment #1 - FDA-482 - Notice of Inspection - Tailwind Nutrition, Inc. - 3 Pages	3

SIGNATURE

Samantha E Rafferty
Investigator
Signed By: SAMANTHA RAFFERTY -S
Date Signed: 09-16-2024 06:52:13