

FDA AUDIT INSPECTION REPORT

Establishment Inspection Report

FEI: 362123456789

Novel Nutrientss PVT. LTD.

EI Start: 07/20/2024

Bengaluru, Karnataka, 560058

EI End: 07/20/2024

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SUMMARY

Assessment	
Operation ID and Name	275951: FY24 Foreign Food Inspection Trip 2024-179
Summary Data	
This is a comprehensive report.	
Inspection Basis	Surveillance

Summary
<p>This comprehensive inspection of Novel Nutrientss PVT. LTD. was conducted on May 20th, 2024, to evaluate compliance with Good Manufacturing Practices (GMPs) under 21 CFR Part 117, Subpart B. The inspection took place at the firm's facility located at 9e/17 Peenya Industrial Area 2nd Phase, Bengaluru, Karnataka, 560058, India, with Subramanian Subbaiyan, the Managing Director, accompanying me during the inspection. The firm, initially established in 2011 as Novel Nutrientss Private, changed its name to Novel Nutrientss PVT. LTD. The company employs 50 full-time staff members and has several US customers, including Green Wave Ingredients USA. The firm reported gross annual sales of \$1.2 million in 2022 and \$1.7 million in 2023, with 70% of products distributed to the United States. The firm operates from a 20,000 square-foot facility. This was the firm's first FDA inspection, so there were no previous observations.</p> <p>During the inspection, several key areas of the firm's operations were reviewed. The pest control measures were examined, and records of pest control activities, conducted twice a month, were reviewed. Employee training manuals and Standard Operating Procedures (SOPs) were checked to review staff training and procedures. The firm's environmental monitoring practices, including methods for sampling and testing potential contaminants within the production environment, were also reviewed. The allergen management programs were reviewed. Sanitation logs and cleaning records were examined. The recall procedures, including the firm's written recall plan and records of any past recalls, were reviewed. Additionally, consumer complaints logs were examined.</p> <p>The firm specializes in the production of nutraceutical ingredients, including their top three products: Moringa Leaf-on Powder, Ashwagandha Root Powder, and Flax Seed Meal Powder. The production processes involve several key steps such as raw material reception, quarantine and sampling, storage, sifting, blending, magnetic particle removal, drying, milling, and packaging.</p> <p>The inspection included a closeout meeting where no significant cGMP violations or sanitation deficiencies were observed; therefore, an FDA Form 483 was not issued. The firm maintains an active Food Facility Registration with the FDA. All records provided during the inspection were paper copies and hard copies, stored in accordance with FDA record management procedures.</p>

Consumer Complaints Review
During the inspection of the firm's complaint files, it was observed that the company maintains a tracking system for all consumer complaints. There were no instances of complaints or indications of complaints that had not been previously reported to the FDA.

Trip Number
2024-179

ADMINISTRATIVE DATA

Establishment Inspection Report

FEI: 3021238902

Novel Nutrientss PVT. LTD.

EI Start: 07/08/2024

Bengaluru, Karnataka, 560058

EI End: 07/08/2024

Administrative Data	
Firm	Novel Nutrientss PVT. LTD.
Physical Address	
Address Line 1	9e/17
City / Province / Country /Postal Code	Bengaluru, Karnataka, India 560058
Phone	(+91) 80-23253578
Mailing Address	
Address Line 1	9e/17
City / Province / Country /Postal Code	Bengaluru, Karnataka India 560058
Email Address	ss@novelnutrient.com
Inspection Date(s)	07/08/2024

FDA Inspection Participants	
Participant Name and Title	
Subramanian Subbaiyan	Investigator

FDA Credentials Were Displayed to the Following Person(s)	
Person's Name and Title	Subramanian Subbaiyan, Managing Director

FMD-145 Recipient and Industry Portal Representative/Most Responsible Corporate Official*		
IPR/FMD Person		
Person's Name and Title	Subramanian Subbaiyan, Managing Director	Industry Portal Representative and FMD-145 Recipient
Email Address	ss@novelnutrient.com	
Mailing Address	The same as the firm's mailing address.	
Phone Number		
*If a corporation		

Guidance Documents Given to the Firm	
During the current inspection, I emailed Mr. Subramanian Subbaiyan, Managing Director, several FDA guidance documents. These included the 'FDA Firm Resources' handout and the 'Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry.'	

HISTORY

Food Firm Registration Status	Current
Hours of Operation	Monday – Saturday 9am-6pm
New or Current Firm Legal Name	Novel Nutrientss PVT. LTD.
Legal Status	Other
State of Incorporation	XX
Year of Incorporation	2011

INTERSTATE (I.S.) COMMERCE

Description of Interstate Commerce	<p>Novel Nutrients Private Ltd engages in the production and distribution of nutraceutical ingredients, with operations geared towards wholesale. Approximately 70% of its product line is exported to the United States. The company coordinates exports through Green Wave Ingredients Inc., located in Los Angeles, CA, which acts as their customer for these transactions. The distributing facility is located at 9e/17 Peenya Industrial Area, 2nd Phase, Bengaluru, Karnataka, 560058, India, and products are delivered to Green Wave Ingredients Inc. at the aforementioned address in California.</p> <p>For this shipment, the logistics of product transportation were managed through sea freight, with relevant documentation provided, including export invoices and bills of lading. The shipment, described in the invoice dated 07/07/2024, included items such as Ashwagandha root powder and Calcium Citrate, with specific details on quantities and batch numbers outlined. The port of loading was Chennai, and the port of discharge was Los Angeles, (Exhibit #1).</p>
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JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

Description of Jurisdiction	<p>Novel Nutrientss PVT. LTD. manufactures and distributes nutraceutical ingredients that are regulated by the FDA, including products such as Ashwagandha root powder, Ashwagandha Root Powder, and Zinc Acid Zinc Powder intended for further processing.</p>
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INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	Subramanian Subbaiyan, Managing Director
Roles and Authorities	Subramanian Subbaiyan is the Managing Director of Novel Nutrientss PVT. LTD. He is present at the facility every day and played an active role during the inspection. He accompanied me throughout the inspection, provided the necessary forms and documents, and facilitated the review of the firm's operations. Subramanian Subbaiyan makes all key decisions for the firm.
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	ss@novelnutrient.com
Mailing Address	The same as the firm's mailing address.

FIRM'S TRAINING PROGRAM

<p>The firm's employee training program includes initial training on standard operating procedures (SOPs) covering food safety, hygiene practices, and equipment handling. New hires undergo this training upon joining the company. Ongoing training sessions are held regularly to update employees on changes in SOPs and regulatory requirements. Training records document attendance and completion of training modules. Employees are periodically assessed to verify their understanding of responsibilities and quality control measures.</p>
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MANUFACTURING/DESIGN OPERATIONS

Process Flow, Operations, and Product Coverage

The process begins with the reception of raw materials, which are inspected for quality upon arrival. Inspection records of the raw materials were reviewed. Once inspected, materials are quarantined and sampled for further testing. The quarantine logs and sampling records were examined.

The materials are then dried to achieve the required moisture content. The drying process was observed, and moisture content logs were reviewed. Following drying, the materials are milled to achieve the desired particle size. The milling process was observed, and equipment logs were reviewed to ensure the proper functioning of the milling machinery.

Next, the ingredients are formulated into blends based on specific recipes. The formulation process was observed, and formulation logs were reviewed. This is followed by the blending stage, where the ingredients are blended. The blending process was observed, and blending logs were checked to ensure consistency.

Quality control inspections are conducted, and products are labeled accordingly. Inspection and labeling records were reviewed to ensure that products meet the required standards. Sanitation procedures involve regular cleaning schedules documented in the firm's SOPs. Equipment is cleaned in place (CIP), with the cleaning process including the use of chemicals. The sanitation and cleaning procedures were observed, and related records were reviewed.

Final products are packaged for further manufacturing, not for retail sale. The firm conducts finished product testing and provides Certificates of Analysis (COAs) to customers. The documentation related to these processes was reviewed.

MANUFACTURING CODES

The manufacturing code system at Novel Nutrients Pvt. Ltd. utilizes a combination multiple factors. Each product is assigned a unique batch number based on this system.

RECALL PROCEDURES

The firm's recall procedures involve a written plan that outlines steps for identifying and removing potentially contaminated or non-compliant products from the market. The process includes initiating a recall based on internal quality checks, customer complaints, or regulatory notifications. The firm ensures traceability through detailed records of lot numbers, production dates, and distribution records. Notification protocols are in place to inform relevant parties, including customers and regulatory authorities. The recall plan includes conducting mock recalls periodically to test the effectiveness of the procedures and ensure efficient tracking and removal of affected products.

REFUSALS

Inspection Refusals
No refusal

GENERAL DISCUSSION WITH MANAGEMENT

A closeout meeting was held with Mr. Subramanian Subbaiyan, Managing Director on 07/08/2024. No significant cGMP violations or sanitation deficiencies were observed; therefore, an FDA 483, Inspectional Observations was not issued at the close of this inspection. It was discussed with the firm that they should continue to register with the FDA biannually.

SAMPLES COLLECTED

No samples were collected.

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	Description	Number of Pages
1	Records and SOP of Quality Management...	3

Establishment Inspection Report

FEI: 3021238092

Novel Nutrientss PVT. LTD.

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SIGNATURE

