



| <b>Establishment Information</b>                                     |  |
|--|--|
| Facility Name<br><b>OLDE VIRDEN'S</b>                                | Facility Type<br><b>Fruit, Nuts &amp; Vegetable Products</b>             |
| Facility ID #<br><b>NFRY-A9FLAP</b>                                  | Facility Telephone #<br><b>865 599-3202</b>                              |
| Facility Address<br><b>446 Mountain Dr<br/>Gatlinburg , TN 37738</b> |  |
| Licensee Name<br><b>CHRIS &amp; ALLYSON VIRDEN</b>                   | Licensee Address<br><b>446 Mountain Dr<br/>Gatlinburg , TN<br/>37738</b> |

| <b>Inspection Information</b>     |                                      |                                 |
|-----------------------------------|--------------------------------------|---------------------------------|
| Inspection Type<br><b>Routine</b> | Inspection Date<br><b>12/10/2019</b> | Total Time Spent<br><b>5.00</b> |

| <b>Violation Counts</b>           |                                       |                                 |  |
|-----------------------------------|---------------------------------------|---------------------------------|--|
| # Critical Violations<br><b>0</b> | # Non-Critical Violations<br><b>1</b> | # Repeat Violations<br><b>0</b> |  |

| <b>Details</b>  |   |  |   |
|---|---|--|---|
| Products Produced During Inspection<br><b>Packaging of Dried<br/>Pepper Blend</b> | Authority to Inspect TN code 53-1-208 or FDA 482 for FDA contract<br><b>FDA 482</b> | GMP Notice or FDA 483 when FDA Contract inspection Issued<br><b>No</b> | Name and Title of Representative<br><b>Allyson Virden-Owner</b> |

| <b>Warewashing Info</b> |                     |              |     |                |                |             |
|-------------------------|---------------------|--------------|-----|----------------|----------------|-------------|
| Machine Name            | Sanitization Method | Thermo Label | PPM | Sanitizer Name | Sanitizer Type | Temperature |
| <b>3 bay sink</b>       | <b>chemical</b>     |              |     |                |                |             |

**OPERATOR** - Items cited identify violations of State Statute which must be corrected by the next routine inspection or such shorter period of time as may be specified by the Regulatory Authority. Failure to comply with any time limits for corrections specified in this NOTICE may result in cessation of your operation and/or civil penalties, TCA 53-1-103; 58-8-217; 4-3-204; 8-913.10. Commissioner must be notified within 15 days.

| <b>Observed Critical Violations</b> |
|-------------------------------------|
| Total # <b>0</b>                    |
| Repeated # <b>0</b>                 |

| <b>Observed Non Critical Violations</b>   |
|---|
| Total # <b>1</b>  |
| Repeated # <b>0</b>   |
| <b>2.06 - Observed Violations - Ladders and walkways over exposed product lines are protected to prevent potential contamination.</b> |
| Observation: observed several locations where unfinished wood is present located in the processing room                               |
| Corrective Action(s):   |

| <b>In Compliance</b>   |
|--|
| Section 1.01 1. - Employees with obvious sores, infected wounds, or other infectious illnesses are not in contact with exposed food products, packaging or food contact surfaces. - In |
| Section 1.02 1. - Employees adhere to proper hygiene practices and maintain personal cleanliness. - In   |

Section 1.03 1. - Outer garments, suitable to the operation, are worn to protect against allergen, cross-contamination and against food or food contact surface contamination. - In

Section 1.04 1. - Gloves, if worn, are intact, clean and sanitary - In

Section 1.05 1. - Appropriate and effective hair restraints are worn where open food items are present. - In

Section 1.06 1. - Clothing and other personal items are stored in designated areas where food is not exposed or where equipment or utensils are washed - In

Section 1.07 1. - Eating, chewing gum, drinking and use of tobacco are confined to designated areas. - In

Section 1.08 1. - Exposed jewelry, other than plain wedding and is not observed. - In

Section 2.01 2. - Roads, yard, and grounds are properly maintained. - In

Section 2.02 2. - Equipment, litter or vegetation is not within the immediate vicinity of the plant that may constitute and pest harborage site - In

Section 2.03 2. - Exterior areas where water can pool were not observed - In

Section 2.05 2. - Sufficient space in storage and production areas for maintenance and sanitation - In

Section 2.07 2. - Lighting is adequate. Light fixtures and all glass in receiving, shipping and production areas are covered or otherwise protected. - In

Section 2.08 2. - Adequate screening or other protection is provided for defense against pests. Doors and windows are closed or screened. No gaps are present. Exterior doors are self-closing - In

Section 2.09 2. - Adequate ventilation or equipment is used to control and/or minimize dust, odors and vapors in areas where they may cause allergen cross-contamination. Fans or other blowing equipment are used in a manner to minimize the potential for allergen-contamination of food, packaging materials or food-contact surfaces. - In

Section 2.10 2. - Condensate from fixtures is not observed to contaminate food, food-contact surfaces or food packaging materials - In

Section 3.01 3. - Water supply is adequate and derived from adequate source (Document results and date of last potable water test.) - In

Section 3.02 3. - An appropriate system is in place to dispose of sewage/wastewater - In

Section 3.03 3. - Drains are clean and adequate to prevent pooling on floor - In

Section 3.04 3. - Water lines and hoses protected against backflow or cross-connections between potable and non-potable water systems. - In

Section 3.05 3. - Hand wash stations are appropriately located, properly stocked, functioning, and accessible. - In

Section 3.06 3. - Toilet facilities are provided to employees and are adequate, readily accessible, stocked and cleaned - In

Section 3.07 3. - Hand wash fixtures designed to protect against recontamination of clean, sanitized hands. - In

Section 3.08 3. - Rubbish and offal disposal is disposed of and stored to minimize the development of odor and the potential for pest activity. Outsider waste containers have lids. - In

Section 3.09 3. - Loading dock areas are clear of debris and spilled products. - In

Section 4.01 4. - Building and fixtures are maintained in a sanitary manner - In

Section 4.02 4. - Substances used in cleaning and sanitizing are appropriate for food manufacturing firms. Record chemicals used verify label/ MSDS. A minimum of 3 chemicals. - In

Section 4.03 4. - Cleaning and sanitizer chemicals are stored in a manner to prevent contamination - In

Section 4.04 4. - All pesticides or toxic chemicals and compounds stored on site are labeled and kept away from food items and packaging - In

Section 4.05 4. - All food-contact surfaces, including utensils are cleaned at an appropriate frequency. The frequency protects against allergen cross-contact and contamination of food. - In

Section 4.06 4. - Food contact surfaces must be cleaned and sanitized prior to use. - In

Section 4.07 4. - There is no evidence of decomposed pest(s) in the interior of the facility. There is no evidence of insects, spiders, rodents or birds on or in any food ingredients, products or packaging materials. Record the name of a pest service and date of last inspection. - In

Section 4.08 4. - Non-food contact surfaces are cleaned at a frequency to prevent microbial, physical or chemical (including allergen) contamination. - In

Section 5.01 5. - Equipment and utensils are designed and constructed to prevent contamination of food products. - In

Section 5.05 5. - Vehicles and equipment used for moving raw materials, finished products and packaging materials are clean and in good condition. - In

Section 6.01 6. - Sanitation of the plant is under the supervision of one or more competent individuals. - In

Section 6.02 6. - Adequate precautions are taken to ensure that production procedures do not contribute to allergen cross contact - In

Section 6.03 6. - Product contamination not observed - In

Section 6.04 6. - Packaging material is food grade - In

Section 6.05 6. - Food that has been contaminated is rejected and segregated...explain the procedure - In

Section 6.07 6. - Food items are stored at the appropriate temperatures - In

Section 6.08 6. - Bulk tanks and containers designed and constructed to protect against contamination - In

Section 6.09 6. - Conditions or practices that may potentially contaminate product, or could lead to product contamination, do not exist. - In

Section 6.11 6. - Food is stored and transported under conditions that will protect against allergen cross-contact and against microbial, chemical or physical contamination - In

## Inspection Score 765

### Comments

- >FDA Contract Inspection; No violations noted from previous FDA Contract Inspection on June 5, 2019.
- >There are no consumer complaints associated with firm to be addressed during inspection
- >Firm has moved to a new location as of Oct 1, 2019. New Address: 4903 Strawberry Plains Pike Knoxville, TN 37914
- >Purpose of visit is to conduct an FDA Contract Inspection, Credentials and FDA 482 presented to Allyson Virden-Owner; Mrs. Virden is Most Responsible Person at Facility; Contact Information: Phone 1-888-544-2998 Email allyson@oldevirdens.com; Mrs. Virden has over 29 years experience in the food industry.
- >Firm is in the process of packaging Red Hot Dried Pepper Blend in a 1 oz non flexible plastic container with a heat seal and plastic screw on cap, not commercially sterile product
- >Firm is a Manufacturer of dried pepper blends, that offers 4 different blends of dehydrated, crushed peppers.
- >Firm had a water activity analysis performed on product by BCN Research Laboratories (Rockford, TN) on 4/29/19  
-1 oz Bottle Olde Virden's Red=0.2917      1 oz Bottle Olde Virden's Spicy=0.2490
- >Firm offers products to be packaged in 1 oz, 1.5 oz, and 4.5 oz plastic bottles with a heat seal and plastic screw on cap.
- >Firm distributes product themselves and has Boyle Family Foods (Nashville, TN) distribute product. Firm has a distribution area in the state of TN, AL, KY, NC, & VA.

#### General Information:

- Facility Size: 1,200 sq ft
- Number of Employees: 2
- Hours of Operation: M-F 9 am till 3 pm
- Transport Vehicle: 1 Company Owned transport vehicle & Common Carrier
- Annual Dollar Amount: \$49,000
- Legal Status: LLC
- History: Firm has been in business since 2014; moved to present location since Oct 2019

#### Jurisdiction:

- Interstate Business Received: 20%
- Interstate Business Sold: 10%
- Wholesale: 60%

#### Process Observed:

- Removal of finished product from bulk storage container, pouring product into container using a food grade funnel, heat seal applied on bottle, screw on cap applied on bottle , and labeled

#### Raw Ingredients Received:

- Santana Produce (Grainger, TN)
- Sonshine Produce (Knoxville, TN)

#### Finished Product Code Dating:

- Firm provides a Best By date on each bottle (Example: 060322)
- \*Recommend firm to develop a traceability system using Best By Date

#### Documents Reviewed:

- Current FDA Registration (Expires 12/31/20)
- Consumer Complaint Procedure (No Complaints Documented)
- Production Log (Viewed July 2 thru Dec 4)
- Sanitation and Equipment Cleaning Schedule (Viewed July 2 thru Dec 4)
- 2018 Water Quality Report (Knoxville Utility Board)
- Process Flow Chart
- Labels
- Letters of Approval for Packaging (Tri-Delta Plastics Hillsborough, NJ) 2014
- Pest Control Log (All About Bugs) 11/13/19; No Activity Recorded
- MSDS for cleaning chemicals in use

#### Recommendations:

- Firm has not conducted a Hazard Analysis and is not operating under a written Food Safety Plan, recommendation made to firm to develop Food Safety Plan

- Firm does not have a documented Product Recall Plan, recommendation made to firm to develop Product Recall Protocol
- Firm does not have an Employee Training Program, recommendation made to firm to develop an Employee Food Safety Training, and to maintain documentation of Employee Training
- Firm does not have an established GMP Program at present time, Develop Good Manufacturing Practices for firm
- Firm does not have a Preventive Maintenance Program, recommendation made to firm to develop Preventive Maintenance Schedule on Equipment, Facility, Etc.
- Receive Food Safety Certification

FDA Documents Left:

- FSMA Final Rule Preventive Controls
- FSMA Fact Sheet Final Rule Mitigation Strategies to Protect Against Intentional Adulteration
- FSMA Final Rule Sanitary Transportation
- Reportable Food Registry
- Employees First Line of Defense
- Guidance for Food Security/Defense

Firm may qualify for modified Preventive Controls due to annual sales, provided information below for firm to follow-up on Preventive Controls requirements

-[www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/default.htm](http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/default.htm).

Documents Received:

- Product List
- 3 Sample Labels

Allergens were discussed during inspection, firm is not using either of the "Big 8" Allergens in production, No Allergens Present  
 No Environmental Monitoring  
 No refusals encountered during inspection

Discussed violation with Mrs. Virden and she expressed violation will be corrected within 10 days. No written response required, FDA 483 was not issued to firm

Disclaimer

Person in Charge



Allyson Virden

Inspector



Blake Loveday

Facility ID #  
NFRY-A9FLAP

FEI Number  
3010861309

Inspection Date  
12/10/2019

Inspection Type  
Routine

**TENNESSEE DEPARTMENT OF AGRICULTURE**

Division of Consumer & Industry Services

**INSPECTION FORM**

**FDA Contract Inspection Form - To be used with Manufacturing and Warehouse Coversheet Form for Contract inspections**

|  |   |                                      |   |
|--|---|--------------------------------------|---|
| <b>Pre-Inspection: Information from the eSAF Database</b>  |   |                                      |   |
| Significant Findings for Last FDA Inspection<br>No significant findings from previous FDA inspection on June 5, 2019 |   |                                      | Are There Any FDA Compliants Not Worked<br>No       |
| <b>Inspection: Information collected on-site</b>   |   |                                      |   |
| Interstate Business Received<br>20%  | Interstate Business Sold<br>10%   | Interstate Business Wholesale<br>60% | Approximate Annual Dollar Volume<br>25,000 - 49,999 |
| Number of Employees<br>2   | How Are Complaints Handled<br>(1) Date of Call (2) Customer Name (3) Phone Number (4) Email Address (5) Reason for Complaint/Call (6) Action Taken (7) Date of Resolved | Transport Vehicles<br>1              | How Are Product Recalls Handled<br>N/A              |
| <b>Written Recall Handling Protocol</b>  |   |                                      |   |
| Documentation Available<br>No  | Reviewed<br>No  |                                      |   |

**Guidance Documents are at the Firm (If No, Leave Appropriate Document)**

|   |   |   |   |
|---|---|---|---|
| RFR-Reportable Food Registry<br><b>Yes</b>  | Guidance for Food Security/Defense<br><b>Yes</b>                            | Employee First Alert Guidance<br><b>Yes</b> | Is Firm Registered with FDA (Bioterrorism Registration)<br><b>Yes</b> |
| FDA (FSMA) Fee Assessment Information Form Left with Facility<br><b>No</b>  |   |   |   |
| Number of Labels Collected<br><b>3</b>  | Do Labels meet the requirements of Food Drug and Cosmetic Act<br><b>Yes</b> |   | Has Firm Applied for Exemption<br><b>No</b>                           |
| Product Coding<br><b>28YGT99; Spices, flavors, and salt not mentioned elsewhere, plastic synthetic packaging, not commercially sterile</b>                                    |   |   |   |
| Manufacturing Product Description<br><b>Firm is packaging Red Hot Sprinkle dried pepper blend in 1 oz non flexible plastic bottle with heat seal and plastic screw on cap</b> |   |   |   |

**CIS FM5**

**Rev. 1, March 2016**