



Establishment Information	
Facility Name WISE BUTTER	Facility Type Community Kitchen 2
Facility ID # DONL-C4EGYA	Facility Telephone # 615 337-6117
Facility Address 975 Main St Nashville , TN 37206	
Licensee Name WENDY F. BARRETT	Licensee Address 108 Lutie St Nashville , TN 37210

Inspection Information		
Inspection Type Routine	Inspection Date 10/26/2021	Total Time Spent 2.00

Violation Counts			
# Critical Violations 0	# Non-Critical Violations 0	# Repeat Violations 0	

Details			
Products Produced During Inspection Dark Wild Flower Honey Butter	Authority to Inspect TN code 53-1-208 or FDA 482 for FDA contract FDA 482	GMP Notice or FDA 483 when FDA Contract inspection Issued No	Name and Title of Representative Ms. Wendy French Barrett, Owner

Equipment Temperatures	
Description cooler	Temperature (Fahrenheit) 34.7

Warewashing Info						
Machine Name	Sanitization Method	Thermo Label	PPM	Sanitizer Name	Sanitizer Type	Temperature
3 Compartment Sink	Chemical			Autochlor Solution QA	Quat	

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.

Observed Critical Violations
Total # 0
Repeated # 0

Observed Non Critical Violations
Total # 0
Repeated # 0

In Compliance
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 2.04 2. - Interior floors, walls, and ceilings are constructed of materials that can be adequately cleaned and maintained in good repair. - 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 5.02 5. - Instruments and equipment are properly maintained and calibrated. - In

Section 5.03 5. - Freezer and cold storage areas are maintained at appropriate temperatures and fitted with temperature measuring devices. - 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 6.06 6. - Products scheduled for rework are clearly identified to prevent allergen cross contamination - 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

Not Observed

Section 6.12 6. - Firm is operating under a food safety plan, such as a HACCP. Document CCPs if applicable. - N/O

Inspection Score 780

Comments

This is a contract FDA inspection. Conducted by Bridgette Strickland of the Tennessee Department of Agriculture. Credentials were presented to Ms. Wendy French Barrett Owner, (wendy@wisebutternashville.com) most responsible person on site. **FDA 482 was emailed to Ms. Barrett and receipt was confirmed. Previous FDA inspection (TDA contract inspection dated 6-11-21) resulted in the following finding.**

21CFR117.10(b)(4) - No unsecured, exposed jewelry, other than a plain wedding band is not observed
Observation: Observed Ms. Barrett wearing rings with stones during production

Firm rents a production space from Citizen Kitchens Commercial Kitchen. Located at 975 Main Street Nashville, TN. Firm has been at this location since 2018. Firm produces on an as needed basis. Firm has 2 employees. Firm produces flavored butters.

Firm currently sells product at Green Door Gourmet and other small local stores in Nashville. Ingredients are purchased from Restaurant Depot and Hatcher Dairy. Inspector advised firm to obtain letters of guarantee from ingredient manufacturers. Packaging is purchased from Eco Products. Inspector viewed website letter stating round deli portion cups are cold food friendly. Inspector advised firm to obtain a letter stating containers meet FDA food safety requirements.

20% of ingredients are sourced interstate, 90% of business is wholesale and 0% of business is sold interstate.

In the event of a recall- Determine scope of recall, notify regulatory, recover all affected products and dispose, document collection and disposal. Terminate when recall is complete.

Complaints are handled- When complaint is received item will be replaced or exchanged. Investigate complaint and respond to customer.

Inspector viewed written SOP for recall dated 2016 and for production. Inspector advised firm to create additional SOP's on receiving, storage and delivery, allergen handling, sanitation procedures and traceability. Inspector viewed the Kitchen Contract that included the following GMP's: Employee Hygiene, Illness Policy, Hand Washing and Eating and Drinking in designated areas.

Ms. Barrett completed Basic Food Safety Training from Metro Health on 8-11-15 and a GMP Internet Training Course in 2013 from Cornell University documents were viewed.

Inspector viewed batch records for roasted garlic basil. Full traceability is done through excel spreadsheets and invoices.

Allergens used include dairy (butter) all products contain this allergen.

Inspector observed production of Dark Wild Flower Honey Butter.

Ingredients are measured and mixed in a large mixer. Once mixed it is transferred to a plastic tub. It is then packaged into small plastic containers using a scoop. Lid and tamper proof tape applied. Finished product has a 30 day expiration date. It is stickered with a 6 digit expiration date. Ex. 112621.

Sanitation is done before, during and after production. Ms. Barrett stated she started a sanitation log. Log was unavailable for view.

Citizen Kitchens is responsible for all equipment maintenance (PM schedule). Kitchen also provides documentation for pest control (monthly), water quality report (yearly), and MSDS for all chemicals on site.

Chemicals on site include Autochlor Pot and Pan Detergent, Autochlor Solution QA Sanitizer and Mach Turbo Dry Mate.

Viewed FDA registration application dated 5-19-21.

Firm stated sales are \$0 – 24,999 annually.

The following exhibits were provided to the inspector by Ms. Barrett:

Exhibit 1- Current product list

Exhibit 2-3x Product label 4 ounce Dark Wild Flower Honey Butter

TN Code 53-1-208, Employees First Toolkit, Reportable Food Registry, FDA Registration packet, Food Security Guidance for Industry, Suspicious Activity, Small Entity Compliance Guide, Final Rule on Preventative Controls, Protecting Against Intentional Adulteration, and Sanitary Transport of Human and Animal Foods were previously discussed and emailed with Ms. Barrett.

Inspector discussed creating a food safety/defense plan. The following links were provided:

<https://www.fda.gov/food/food-defense-tools-educational-materials/food-defense-plan-builder>

<https://www.fda.gov/food/food-safety-modernization-act-fsma/food-safety-plan-builder>

Inspection was reviewed with and emailed to Ms. Barrett (wendy@wisebutternashville.com). FDA 483 was not issued.

No signature required due to COVID-19 restrictions

Disclaimer

Person in Charge

Inspector



Bridgette Strickland

Facility ID #
DONL-C4EGYA

FEI Number
3012161295

Inspection Date
10/26/2021

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

Pre-Inspection: Information from the eSAF Database

Significant Findings for Last FDA Inspection
Previous FDA inspection (TDA contract inspection dated 6-11-21) resulted in the following finding.
21CFR117.10(b)(4) - No unsecured, exposed jewelry,

Are There Any FDA Compliants Not Worked
No

other than a plain wedding band is not observed
 Observation: Observed Ms. Barrett wearing rings with stones during production

Inspection: Information collected on-site

Interstate Business Received 20%	Interstate Business Sold 0%	Interstate Business Wholesale 95%	Approximate Annual Dollar Volume 0 - 24,999
Number of Employees 2	How Are Complaints Handled When complaint is received item will be replaced or exchanged. Investigate complaint and respond to customer.	Transport Vehicles 0	How Are Product Recalls Handled In the event of a recall- Determine scope of recall, notify regulatory, recover all affected products and dispose, document collection and disposal. Terminate when recall is complete.

Written Recall Handling Protocol

Documentation Available Yes	Reviewed Yes
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Guidance Documents are at the Firm (If No, Leave Appropriate Document)

RFR-Reportable Food Registry Yes	Guidance for Food Security/Defense Yes	Employee First Alert Guidance Yes	Is Firm Registered with FDA (Bioterrorism Registration) Yes
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FDA (FSMA) Fee Assessment Information Form Left with Facility
No

Number of Labels Collected 1	Do Labels meet the requirements of Food Drug and Cosmetic Act Yes	Has Firm Applied for Exemption No
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Product Coding
09 A G T 01

Manufacturing Product Description
Butter Products / Plastic, Synth / Packaged Food (Not Commercially Sterile) / Butter (Plain or Whipped)