



HUMAN AND ANIMAL FOOD  
INVESTIGATIONS BRANCH II  
580 S. High Street  
COLUMBUS, OH 43215  
614-227-1100

08/06/2019

Flavorcraft Industries Inc  
2123 Watterson Trl  
Louisville, KY 40299-2428  
US

Reference: Inspection Date(s): 06/11/2019 - 06/11/2019

Location: Flavorcraft Industries Inc  
2123 Watterson Trl  
Louisville, KY 40299-2428  
US

Dear Dear CEO, Jan H. Venter :

A state agency contracted by the U.S. Food and Drug Administration (FDA) conducted an inspection at your premises on the referenced locale and date(s).. Effective April 1, 1997, when the Agency determines an inspection is closed under 21 C.F.R. 20.64 (d)(3), FDA releases a copy of the inspection report to the inspected firm.

You will find a copy of the state contracted inspection report or summary attached. FDA may have redacted some information in accordance with the Freedom of Information Act (FOIA) and Title 21, Code of Federal Regulations, Part 20. Firms may request a copy of their FDA inspections completed prior to April 1, 1997 through FOIA.

FDA is working to make its regulatory process and activities more transparent to the regulated industry. Part of this effort is releasing a copy of your inspection report or summary to you, or acknowledging that the state provided you a copy at the close of their inspection.

If there is any question about the released information, feel free to contact us at 614-227-1100.

For more information on the U.S. FDA, please visit our website at [www.fda.gov](http://www.fda.gov).

Sincerely,

**Cheryl A.  
Pifer -S**

Digitally signed by Cheryl A. Pifer -S  
DN: c=US, o=U.S. Government,  
ou=HHS, ou=FDA, ou=People,  
0.9.2342.19200300.100.1.1=1300103  
308, cn=Cheryl A. Pifer -S  
Date: 2019.08.06 07:19:28 -04'00'

FEI: 2000016146

U.S. Food and Drug Administration  
[www.fda.gov](http://www.fda.gov)

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FSS

JUL 2 '19

ROVD

### CONTINUATION INSPECTION REPORT

**ESTABLISHMENT NAME AND ADDRESS**

**DATE INSPECTED**

Flavorcraft, LLC  
2123 Watterson Trail  
Louisville, KY 40299  
Permit # 76067

06-11-19

PER # 2000016146

**INSPECTORS NAME:**

Jay Fillman, R.S.

*Jay Fillman*

**PERSON(S) RECEIVING REPORT:**

Anita Travis, State Compliance Officer  
Kentucky Food Safety Branch

*Anita Travis 7-3-19*

FDA Cincinnati Ohio D.O.

**NARRATIVE:**

**Summary of Findings**

[Redacted]

[Redacted] inspection of this medium-sized formulated acid foods manufacturer on 06-11-19. No bird, insect or rodent activity was noted on this date. There were no items noted that was contrary to the Kentucky FD&C Act. One 32 fl oz (946 ML) On-Time Mixers Key Lime Sour Cocktail Mix label was collected and reviewed for NLEA compliance and no deficiencies were noted. The firm's annual gross sales were estimated at \$1.5 million. The firm reports that 100 percent of sales are wholesale, and 60-70 percent of sales enters into interstate commerce. They were provided the following information prior to the inspection: FDA 482, Key Facts about Preventive Controls for Human Food, FSMA: Final Rule for Mitigation Strategies to Protect Food against Intentional Adulteration; FSMA: Final Rule on Sanitary Transportation of Human and Animal Food and FSMA: Final Rule on Foreign Supplier Verification Programs.  
Follow-up: Routine.

**History of Business**

This firm is a formulated acid foods manufacturer (sauces, dressings, toppings and RTD beverages). This firm is a LLC consisting of Mr. Johan Venter, CEO, Dr. Bryan Allphin, Director of Compliance, Ms. Nikki Bester, Office Manager, Mr. Adam Bester, Production Manager, Ms. Traci Cox, Quality Assurance Manager, and Mr. Darrin Jensen, Warehouse Manager. The firm is located at 2123 Watterson Trail, Louisville, Kentucky 40299. The phone number is 502-240-0076. The mailing address is the same as the physical address. The firm's fax number is 502-240-0650. The firm's email address is [byran.allphin@flavorcraftllc.com](mailto:byran.allphin@flavorcraftllc.com). This firm has 18 employees. The firm production hours of operation

[Redacted]

are 7:00 a.m. – 3:30 p.m. Monday thru Friday. The firm's office hours are 7:00 a.m. – 4:30 p.m. Monday thru Friday.

### ***Individual Responsibility***

Credentials were shown to and an FDA 482 was issued to Dr. Bryan Allphin, Director of Compliance. Mr. Johan Venter, CEO, is the most responsible person at this location. Mr. Venter was not available on this date. Ms. Traci Cox, Quality Assurance Manager joined us. Dr. Allphin and Ms. Cox provided all the information contained in this report. Ms. Cox accompanied me on today's inspection. Any correspondence, including inspection reports should be addressed to Mr. Venter at the aforementioned mailing address.

### ***Facility and Sanitation***

There has been changes to the facility since the last inspection: the Dry Blend room has been changed to a locked alcohol storage room and the Batching Room was remodeled in the Fall of 2017. This firm is housed in a warehouse/light industrial complex. There is a small set of offices that are attached to the production area. The production area is one (1) large (120' x 130') work areas and an attached 10,000 square foot warehouse. The batch building area is located on the right side of the back wall. The cook kettles are on the left side of the back wall. In front of the cook kettles is the bottling line. The three compartment sink and mop sink are located behind the bottling line, on the left hand wall. Across the room from the bottling line there is a work table that is used for re-labeling or small jobs that are done by hand. The warehouse is separated into three (3) areas: packaging materials are on the left wall and first isle; raw materials are located in the two (2) middle rows and the finished products are located in the last row. Allergens are tagged and segregated from the other raw ingredients. All chemicals are stored in a locked area. This firm is on municipal water supplied by the Louisville Water Company and sewer service is provided by the Metro Sewer District. The firm uses quaternary ammonia for sanitizing. Test strips were provided and Ms. Cox demonstrated knowledge in their proper use. Restrooms and hand wash stations were fully stocked and operational. This firm contracts with Terminix of Louisville for their pest control.

This firm has written SSOP's for cleaning the mixers and kettles, which are based on a 3-teir system. Level 1 is rinsing out the kettles and is used for going from one product to another similar product that will not result in the transfer of objectionable flavors or from a mild flavor to a slightly stronger flavor. Level2 is a wet clean where the kettle is sprayed out with a detergent. This is for going from different product types or a stronger flavor to a milder one. Level 3 is a complete cleaning with detergent followed with a sanitizer, which is used between products containing allergens, coloring agents or very strong flavors. All mixers receive Level 3 cleaning at the end of the shift.

This firm has a written HACCP plan. The HACCP plan was reviewed and signed for the current year on July 27, 2018. All of their products are formulated acid products. The firm's HACCP plan identifies three (3) CCP's. CCP #1 Temperature > 185 degrees F, 3 minutes; CCP #2 pH < 4.6; and CCP #3 Foreign

Material. Dr. Allphin stated that all of the products have a pH of 4.6 or below. A review of the lab records showed no inconsistencies and the pH meter is calibrated weekly. This firm is inspected by a 3<sup>rd</sup> party auditor, SQF thru Eagle Certification Group. The most recent was June 2018.

***Firm's Employee Training Program***

The firm conducts all training for new hires in-house. This training covers, but is not limited to GMP's, Food Safety policies & procedures, cleaning & sanitation procedures, HACCP overview, Food Hygiene, Biosecurity & Food Defense. The firm has written documentation when the training is successfully completed. The firm additionally conducts In-time Training sessions with the employees when necessary.

***Raw Materials, Operations and Manufacturing Procedures***

This firm has an Approved Supplier Program in which all ingredients received with C of A's for all products. Main suppliers of raw ingredients include: Food Guys, Portland, OR and Skidmore Sales & Distributing, Cincinnati, OH.

Ingredients are assembled in a batch building area. Ingredients are weighed, labeled and stored on carts. Allergens are handled with color coded scoops and are weighed out in color coded buckets. Batches are moved to the mixing area. Products are cooked in one of three kettles. Product is pumped from the cook kettle to a holding kettle. The product is pumped from the holding kettle to the filling machine. Plastic jugs or glass bottles are loaded onto the bottling line, where the container is filled, capped, ran thru a bottle rinse, labeled, receives a product code and moved to packaging. Here bottles are placed into a box by hand. The boxes are then sealed with tape and placed onto a pallet. The pallets are then moved to the storage warehouse to await distribution.

***Promotion and Distribution***

The firm produces approximately 300 products for 60-80 customers. Some products are shipped nationwide, but most of the company's distribution is regional (MI, NC, IL, OH and KY). The firm's largest accounts include RMH Franchise (marina sauce), Stanz Food Service, South Bend, IN; Ole Ray's, Louisville, KY; Bottoms Up, Dallas, TX and Morris Kitchen, Inc, Brooklyn, NY.

***Manufacturing Code***

The firm places a manufacturing code on all products. The coding system has been changed since the previous inspection. Previously the code had an eight - digit lot number. The new coding system has added a letter to indicate the production the product was run on. An example of today's On-Time Mixers Key Lime Sour Cocktail Mix is: 19061101A

19 - indicates the year  
06 - indicates the month  
11 - indicates the day  
01 - indicates the batch  
A - indicates the production line.

#### ***End Product Testing***

The firm contracts with MicroBac of Maryville TN for end product testing.

#### ***Allergens***

This firm has written allergen control program. Raw allergen ingredients are identified, tagged and stored separate from other non-allergen ingredients.

#### ***Environmental Swabbing***

This firm's lab does micro testing (ATP swab testing). This is done randomly after Level 3 cleaning of equipment. Testing is done for aerobic bacteria & coliforms. Testing is done at a minimum of 2 x's per month. Recent testing noted June 6, 2019 – Filler Heads; May 23, 2019 – Buckets with Nozzles and May 21, 2019 – Medium Kettle (Interior).

#### ***Pest Control***

This firm contracts with Terminix of Louisville, KY for their pest control. The facility is service on a bi-weekly basis. The most recent service was on 05-24-19. There was no evidence of insect, bird or rodent activity noted on this date.

#### ***Complaints***

The firm stated that they have received no complaints since the last inspection.

#### ***Recall Plan***

Mr. Venter and Dr. Allphin are the recall coordinator for the firm. The firm conducts 2 mock recalls annually.

***Objectionable Conditions***

No objectionable conditions were observed during this inspection. [REDACTED]  
[REDACTED]

***Refusals***

No refusals were encountered during the inspection.

***Discussion with Management***

The inspection was reviewed and read aloud to Dr. Allphin and Ms. Cox and they were in agreement. Ms. Cox signed the inspection and I issued a DFS 220 at the close of the inspection. The company has registered their firm with the FDA concerning BT issues. I informed the firm that under the new FSMA regulations that they would be required to BT register biannually. The following documents were left with the firm during the course of this inspection.

1. Key Facts about Preventive Controls for Human Food
2. FSMA: Final Rule for Mitigation Strategies to Protect Food against Intentional Adulteration
3. FSMA: Final Rule on Sanitary Transportation of Human and Animal Food
4. FSMA: Final Rule on Foreign Supplier Verification Programs

Management was cooperative.

***Exhibits***

- #1 FDA 482
- #2 DFS 220
- #3 Flavorcraft, LLC: Process Step Hazard Analysis (Line A RTD Beverages)
- #4 Flavorcraft, LLC: HACCP Plan/CCP Summary
- #5 Flavorcraft, LLC: One 32 fl oz (946 ML) On-Time Mixers Key Lime Sour Cocktail Mix label