

Establishment Inspection Report

Cava Foods LLC
Laurel, MD 20708-1431

FEI: **3009428924**
EI Start: 12/18/2017
EI End: 12/19/2017

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SUMMARY

This compliance follow-up inspection of Cava Foods, LLC located at 13250 Mid Atlantic Blvd Ste. 100 Laurel, MD 20708-1431, a manufacturer of ready to eat hummus and dipping sauces was conducted in accordance with Preventive Controls, 21 CFR 117Subparts A, B, C, and F, BLT-DO FY 18 Work Plan, and eNspect Operation ID 61743. This was a Preventive Controls inspection.

The previous inspection was a joint inspection conducted by FDA and Maryland Department of Health (MDH) on 3/20-23/2017, and covered current good manufacturing practices, hazard analysis and risk-based preventive controls, training, and supply chain program. Processes covered include receiving and cold storage of raw ingredients, rinsing of chick peas, production of hummus, including roasting of eggplants, grinding of chickpeas, and additions of other ingredients, including tomato paste, lemon juice, and red peppers, packaging of finished product into 8oz containers and 12lb bulk bags, and storage of finished product.

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Records reviewed include: the firm's food safety plan, process hazard analysis for hummus products, daily sanitation records, sanitation verification records, supplier verification records, pest control records, manufacturing records, incoming interstate records for chickpeas, outgoing interstate records for finished product hummus, and employee training records.

An FDA 483, "INSPECTIONAL OBSERVATIONS" was not issued to firm management during the previous inspection, but the inspection was classified VAI because seven environmental samples taken during the inspection were positive for *Listeria monocytogenes*. Six items were discussed with management. Items 2, 4, 6, and 7 were corrected on-the-spot during the previous inspection. Corrections to items 5 and 8 were verified during the current inspection

1. An ingredient hazard analysis was not performed and the firm did not have a document that listed the hazards requiring preventive controls, their monitoring, verification, validation, and record keeping procedures, and their parameter values.
2. In the steps listed on the flow chart and process hazard analysis, an intermediate refrigerated storage step is missing between the "Roasting/Cook/Blend/Sauté" step and the "Assemble/Mixing" step.
3. The firm's process hazard analysis documents the steps during manufacturing, but does not include the specific hazards to be controlled for each step. For example, instead of identifying which biological hazard that will be introduced or controlled at a specific step, it documents only "Vegetative pathogen spores such as listeria"
4. The firm's process hazard analysis did not consider the ingredient storage, finished product storage, and refrigerated shipping steps as steps where hazards could be introduced or controlled.
5. There is no metal detector preventive control for products packaged in 12-pound bulk bags, such as hummus and crazy feta.
6. (b)(4) sanitation checks were not verified within seven days of the record being created.
7. There is no documentation of (b)(4) checks of the raw ingredient and finished product storage coolers.
8. Floors are in disrepair.

The current inspection was a joint FDA-MDH inspection conducted on 12/18-19/2017 to assess the firm's compliance following a Regulatory Meeting that was held with the firm on 6/15/2017. The inspection was limited in scope and covered the firm's hazard analysis, preventive controls plan, and

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food safety plan, new and updated Standard Operating Procedures (SOPs), sanitation, and Good Manufacturing Practices. Processes covered were the storage of raw materials (chickpeas, lemon juice, tahini, garlic, and salt), grinding of chickpeas, ingredient mixing, and finished product filling, labeling, metal detection, and storage. Records reviewed included the firm's food safety plan documents, temperature monitoring records, environmental sampling and product sampling records, sanitation records, certificates of analysis, production records, corrective action records, and process control records.

An FDA 483, "INSPECTIONAL OBSERVATIONS" was not issued during the current inspection, but three items were discussed with firm management at the close of the inspection on 12/19/2017: 1. Jalapeño slicing blades in a cleaned equipment area were observed with residue adhering to their surfaces; 2. Employees were observed on the mixing and filling lines handling the outside and inside (food-contact surfaces) of equipment and utensils without changing gloves; and 3. The firm's ingredient hazard analysis did not identify the hazards of *Shigella spp.*, *S. aureus*, and *Giardia* in raw peeled garlic, and the hazard of mycotoxin in tahini. Items 1 and 2 were corrected on-the-spot, and management promised corrections to the hazard analysis.

(b) (3) (A)

No refusals were encountered and there were no samples collected.

ADMINISTRATIVE DATA

Inspected firm: Cava Foods LLC
Location: 13250 Mid Atlantic Blvd
Laurel, MD 20708-1431
Phone: 240-350-8813
FAX: 301-984-1681
Mailing address: 13250 Mid Atlantic Blvd Ste 100
Laurel, MD 20708-1431
Dates of inspection: 12/18/2017-12/19/2017
Days in the facility: 2
Participants: **Jessica D. Weber, Investigator, HAF2E, Baltimore District Office**

Non-FDA Participants:

Sherry Donovan-Morris, Regional Environmental Health Specialist, Maryland Department of Health

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On 12/18/2017, I, Investigator Jessica D. Weber, displayed my credentials and issued an FDA 482, "NOTICE OF INSPECTION" to Mr. Christopher F. Penny, Chief Operating Officer (Cava Foods, LLC) (**Attachment 2**) and most responsible individual present at the firm. Ms. Donovan-Morris entered the firm on the authority of the State of Maryland.

Cava Foods, LLC is also inspected by the Maryland Department of Health.

An FDA 483, "INSPECTIONAL OBSERVATIONS" was not issued at the close of the current inspection on 12/19/2017.

I provided the firm with documents regarding the Food Safety Modernization Act, the Reportable Food Registry, and Sanitary Transportation.

This was a joint inspection with Maryland Department of Health Regional Environmental Specialist Sherry Donovan-Morris. Ms. Donovan-Morris was present for the duration of the current inspection.

I, Investigator Jessica D. Weber, wrote all sections of this report. "We" refers to me and Ms. Donovan-Morris.

HISTORY

The firm's history has not changed since the previous inspection.

The firm's production days are (b)(4), (b)(4), and (b)(4). The preparation operations mostly take place in the firm's kitchen and involve roasting, blanching, and cutting ingredients in preparation for production.

INTERSTATE (I.S.) COMMERCE

There have been no changes to the firm's receipt and shipment of ingredients and finished products in interstate commerce.

I collected a Bill of Lading, dated 12/15/2017, that documents the shipment of finished hummus from the firm's contract (b)(4) in (b)(4) to a distribution center in (b)(4) (**Exhibit 1**).

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JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

FDA's jurisdiction of the firm's operations has not changed since the previous inspection. The firm continues to manufacture ready-to-eat hummus and dipping sauces that are shipped in interstate commerce both to retail grocery stores and the firm's retail food establishments.

The firm's labels were reviewed during the previous inspection. The labels have no changed since the previous inspection.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

The firm's management has not changed since the previous inspection.

Mr. Michael O. Boamah, Food Safety and Quality, stated he has been with Cava Foods, LLC for approximately five years. Mr. Boamah stated he has held the title of Food Safety and Quality for approximately one and a half years. Mr. Boamah stated he held the title of Plant Manager for approximately three years, while operating from the previous location in Rockville, MD. Mr. Boamah stated his daily responsibilities include (b)(4) tests of chemical concentrations throughout the firm, testing of finished product, ensure SOPs are followed, performing (b)(4) tests (b)(4) and performing environmental monitoring throughout the firm. Mr. Boamah stated he has no direct reports and he reports directly to **Mr. Jason R. Huck, General Manager**.

Mr. Jason R. Huck, General Manager, stated he has been with Cava Foods, LLC since January 2017. Mr. Huck stated he is the most responsible individual at the inspected location. Mr. Huck stated his daily responsibilities include assisting the corporate procurement team, assisting with end of production sanitation as needed, hands on- on the job training, and overseeing production and facilities operations. Mr. Huck stated he has the authority to hire and fire individuals at his location and make corrections to deficiencies identified at his firm. Mr. Huck stated he has three direct reports and **Mr. Christopher F. Penny, COO** is his direct supervisor.

Mr. Christopher F. Penny, COO Cava Foods, LLC, stated he has been with Cava Foods, LLC since approximately September 2015. Mr. Penny stated his daily responsibilities include overseeing day to day sales operations, and distribution of Cava Products. Mr. Penny stated he is currently responsible for the distribution team at the inspected location. Mr. Penny stated he has the authority to hire and fire individuals as well as make corrections to deficiencies identified at Cava Foods, LLC. Mr. Penny stated he has four direct reports, with three being located at the Laurel, MD location and one located in Los Angeles. Mr. Penny stated his direct supervisor is **Mr. Brett Schulman, CEO of Cava Group, Inc.** whose offices are located in Washington, DC.

Mr. Brett Schulman, CEO of Cava Group, Inc. was not present for the current inspection.

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FIRM'S TRAINING PROGRAM

The firm has written and implemented new Standard Operating Procedures since the previous inspection. For those relating to employees (GMPs, sanitation, monitoring, etc.), training has been (b)(4).

The firm has two Preventive Controls Qualified Individuals, Mr. Jason Huck and Mr. Michael Boamah. Management stated that employees participate in GMP training at the start of their employment and thereafter on an as-needed basis. Management stated on the job training is utilized for area specific trainings such as prep kitchen, production and packaging. Management also stated that training for sanitation tasks are performed on the job.

MANUFACTURING/DESIGN OPERATIONS

A process flow diagram and floor plan are attached as **Exhibits 4 and 5**, respectively.

For the purposes of document review, we only covered the firm's traditional hummus. All of the firm's products have a pH (b)(4)



During mixing operations, we observed employees on the mixing line handling both the outside and food-contact surfaces of equipment and utensils without changing gloves (see the **“GENERAL DISCUSSION WITH MANAGEMENT”** section of this report, **Item #1**).

The (b)(4) totes are moved to (b)(4) of the firm's filling machines ((b)(4) and (b)(4) bag filler). During filling operations, we observed employees touching the inside (food-contact) and outside of the 12-pound bags without changing gloves (see the **“GENERAL DISCUSSION WITH MANAGEMENT”** section of this report, **Item #1**).

Previously, the firm's mixers were in close proximity to a wall, they have since been moved off of the wall to allow for easier cleaning. Mr. Huck stated that (b)(4) of the mixers are slated to be removed and replaced with (b)(4) grinder/mixers. The new mixers will (b)(4) Mr. Huck stated that they have already been ordered and will be

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ready in approximately four months. Additionally, totes are currently being stored on pallets in the production area, but Mr. Huck stated there are plans to (b)(4) stands in January 2018. The stands will (b)(4)

Since the previous inspection, the firm has implemented a (b)(4) and no longer allows pallet jacks in the production area. Additionally, Mr. Huck stated that there are plans to purchase a (b)(4) tank, possibly in March 2018. Mr. Huck explained the firm's (b)(4) system and we observed signs throughout the kitchen and processing area that document the scheme.

Color	Area
(b)(4)	(b)(4)
(b)(4)	(b)(4)
(b)(4)	(b)(4)
(b)(4)	(b)(4)
(b)(4)	(b)(4)
(b)(4)	(b)(4)
(b)(4)	(b)(4)
(b)(4)	(b)(4)
(b)(4)	(b)(4)

For a complete list of corrections, improvements, and planned improvements, see the “VOLUNTARY CORRECTIONS” section of this report.

Previously, some of the firm’s hummus and dipping sauces were (b)(4). Mr. Huck stated that now all of the firm’s dipping sauces are (b)(4). Only part of the firm’s hummus is (b)(4).

During a visual inspection of the kitchen, we observed slicing blades in the clean equipment area that Mr. Huck stated were for slicing jalapeños. The blades had residue adhering to their surfaces. (see the “GENERAL DISCUSSION WITH MANAGEMENT” section of this report, Item #2).

I reviewed the firm’s ingredient hazard analysis, process hazard analysis, and preventive controls plan (Exhibits 2 &3). Previously, the firm did not have an ingredient hazard analysis or final preventive controls plan, and had a partial process hazard analysis.

During my review of the firm’s ingredient hazard analysis (Exhibit 2), I observed that the following ingredient or food-related biological and chemical hazards requiring a preventive control were not identified (see the “ADDITIONAL OBSERVATIONS” section of this report, Item 1):

- The biological hazards of *Shigella spp.*, *S. aureus*, and *Giardia* in raw peeled garlic.
- The hazard of mycotoxins in tahini.

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During my review of the firm’s process hazard analysis (**Exhibit 3**), I observed that the following process-related biological hazard requiring a preventive control was not identified (**see the “ADDITIONAL OBSERVATIONS” section of this report, Item 2**):

- Recontamination with environmental pathogens

Previously, the firm did not have an environmental monitoring program. During the previous inspection, FDA environmental sampling revealed seven subsamples that were positive for *Listeria monocytogenes*. The firm implemented an environmental swabbing program immediately after the previous inspection in March, 2017.

Mr. Huck and Mr. Boamah explained the firm’s environmental monitoring program. They stated that approximately (b)(4) are taken from the firm’s (b)(4) production areas. The swabs are taken from primarily (b)(4). Results are received from (b)(4) and if positive results are received, the area is re-cleaned and sanitized. (b)(4)

Since the environmental monitoring program has been in place, problem areas have been identified with the mixing bowl bases and drains. The bowl base has been intermittently positive since July 2017. Mr. Huck explained that he believes it is because the piece of equipment is difficult to clean. He stated that corrective actions included intensified cleaning, resurfacing rusty or rough areas, and finally taking the piece of equipment out of production. He stated that they have been removed from the facility and are being used as engineering samples to design new, more cleanable bases.

The firm’s drains, particularly Drains (b)(4) have had repeat positive samples. The firm has (b)(4) to control the problem. Mr. Huck stated approximately three weeks after the end of the current inspection that the firm has taken approximately (b)(4) samples over a (b)(4) and has not had any positives. Additionally, the firm added a (b)(4) to prevent the formation of biofilms in the drains. Examples of the firm’s corrective action records for these events are included as **Exhibit 6**.

Cleaning and sanitizing operations are conducted (b)(4). (b)(4). After a (b)(4) inspection of the equipment, (b)(4) are taken on (b)(4). Mr. Boamah stated that an initial (b)(4) failure is treated as a correction - the piece of equipment is cleaned again and retested. He stated that if the (b)(4) fails again, it is treated as a corrective action. The firm’s corrective actions for (b)(4) failures include documentation, an investigation, and the involvement of the General Manager (Mr. Huck). We reviewed the firm’s sanitation and (b)(4) logs for October and November 2017 and had no objectionable observations.

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Allergens such as milk are run infrequently and (b)(4). (b)(4) swabs are taken (b)(4) for dairy and gluten.

Certificates of Analysis that include testing for pathogens are collected and reviewed for every shipment of organic chickpeas, tahini, yogurt, feta, chia seeds, sunflower oil, and spices. Every finished lot of product is tested for coliforms and aerobic plate count. Mr. Huck stated that recently, elevated levels of non-pathogenic lactic acid bacteria were discovered in some of the firm's finished products. After investigation, it was determined that garlic could be the culprit, so the garlic is now (b)(4) before use. A copy of the firm's corrective action flow chart and product release matrix are attached as **Exhibits 7 & 8**, respectively.

The firm has installed (b)(4) since the previous inspection. It consists of (b)(4). Mr. Huck showed us examples of the records generated by the system. The system had just become operational during the current inspection, so we discussed options for temperature monitoring, including printing and reviewing records or monitoring by exception.

The firm has (b)(4). For (b)(4), the label is checked at (b)(4). The check documents the presence of the correct label and correct allergen declaration. We reviewed these checks for both filling lines for 12/4/2017 and 12/9/2017 and had no objectionable observations.

During the previous inspection, a metal detector was present and operational on the (b)(4). A metal detector has since been installed on the (b)(4) line. We reviewed examples of metal detector checks for (b)(4) lines and had no objectionable observations.

MANUFACTURING CODES

The firm's product coding system has not changed since the previous inspection.

(b)(4)


For example: Traditional Hummus manufactured on March 22, 2017 that has NOT gone through a (b)(4) process would have a manufacturing code of:

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(b)(4)



16 oz (12lb) bags have a bulk label applied which lists the Product Name, Manufacture Date, Bag #, expiration date and Internal work order number.

COMPLAINTS

The firm’s complaint procedure has not changed since the previous inspection, and the firm has not received illness or injury complaints. There were no complaints listed for the firm in FACTS.

RECALL PROCEDURES

The firm’s recall procedure has not changed since the previous inspection and the firm has not been involved in a recall since the previous inspection.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

An FDA 483, “INSPECTIONAL OBSERVATIONS” was not issued during the current inspection.

ADDITIONAL OBSERVATIONS

Observations not listed on form FDA 483

Your hazard analysis did not identify a known or reasonably foreseeable hazard that required a preventive control:

- The ingredient biological hazards of *Shigella spp.*, *Staphylococcus aureus*, and *Giardia duodenalis* in the ingredient hazard analysis for raw, peeled garlic (**Exhibit 2**).
- The ingredient chemical hazard of mycotoxin in the ingredient hazard analysis for tahini (**Exhibit 2**).
- The process hazard of recontamination with environmental pathogens in the process hazard analysis for hummus (**Exhibit 3**).

During the current inspection, we observed that the hazard of recontamination with environmental pathogens is being controlled with the firm’s sanitation program. Mr. Boamah promised corrections

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within 30 days.

REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

The following items were not included in the “Additional Observations” section because they did not appear to be a preventive controls documentation or system failure.

1. You did not clean and sanitize your utensils or equipment as frequently as necessary to protect against contamination of food.
 - a. During an inspection of your firm’s processing equipment, the jalapeño slicing blades appeared to have residue adhering to their surfaces. These blades were placed in an area that was designated for clean equipment.

Observation status: Corrected

2. You did not conduct operations under conditions and controls necessary to minimize the potential for contamination of food.
 - a. Employees were observed on the 12-pound bag line touching both the outside and inside of plastic bags without changing gloves. The plastic bags are used to hold refrigerated ready-to-eat hummus.
 - b. Employees were observed on the mixing line handling both the outside and food-contact surfaces of equipment and utensils without changing gloves. This line is used to mix refrigerated ready-to-eat hummus.

Observation status: Corrected**ADDITIONAL INFORMATION**

There is no additional information to report for the current inspection.

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SAMPLES COLLECTED

No samples were collected during the current inspection.

VOLUNTARY CORRECTIONS

The firm has made voluntary corrections since the previous inspection. Previously, there was no metal detector preventive control for products packaged in 12-pound bulk bags, such as hummus and crazy feta. A metal detector has been installed on the 12-pound line. Additionally, the firm's floors were in disrepair.

During the previous inspection, Mr. Huck stated that a flooring replacement project was scheduled to start the day after the inspection ended. During the current inspection, we observed that the floors have been replaced in all of the production areas except the coolers and dry storage areas. Mr. Huck stated that the remainder of the floors will be replaced in the spring or summer of 2018.

The following is a list of corrections and improvements made since the previous inspection.

- The firm has a (b)(4) washing table that was previously located in the kitchen. The (b)(4) has been moved to the production room. Now there is adequate space around the machine for cleaning.
- A metal detector was installed on 12 pound line.
- The firm has implemented a (b)(4) program for their employees
- Mr. Huck stated that there are plans to purchase (b)(4) tank to facilitate washing of small equipment. He expected to have the equipment installed in 12 weeks.
- The mixers were moved away from the wall. Now there is adequate space behind the mixers for cleaning operations.
- Mr. Huck stated that there are plans to replace (b)(4) of the firm's existing mixers with (b)(4) models of the same design. He stated that these mixers will be (b)(4) so that when they are discharged, the discharge operation is not taking place near the floor like it currently is. He estimated that the new mixers will be in place in 18 weeks.

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- Mr. Huck stated that he wants to eliminate pallets from entering the production area, so he has purchased (b)(4) stands. (b)(4) will be placed on these stands instead of resting on pallets. The stands are high enough to allow cleaning underneath.
- A (b)(4) has already been ordered and is expected to arrive 1/5/2018.
- Mr. Huck stated that there are plans to install a (b)(4) washer in the wash room, and a (b)(4) chickpea washer, but he did not give a timeframe for installation of these items.
- Currently, the firm uses some fresh produce to manufacture their products. Mr. Huck stated that they are considering using (b)(4) and (b)(4) to replace some of the fresh produce.
- He stated that additional development work had to be done on these items and did not have a timeframe for completion.
- Within the last month, the firm has started to use (b)(4) sanitizer in their drains. Since starting the (b)(4) there have been no positive swabs from the firm's drains.
- Approximately one week ago, Mr. Huck directed the employees to begin (b)(4) equipment soaks using a new type of acid, and also use a (b)(4) acid for post-rinse applications.
- Mr. Huck stated that there are plans to install a (b)(4) machine to replace the (b)(4) 12-pound line. He expected this to be complete in the next 18 weeks.
- Identified LM problem
- The firm conducted an ingredient hazard analysis, expanded their process hazard analysis, and wrote a preventive controls plan.
- A (b)(4) system has been installed for the firm's coolers.
- Mr. Boamah updated and added items to the firm's sanitation monitoring form.
- Immediately before the current inspection, Mr. Huck directed employees to ensure that items moving in and out of the coolers are (b)(4)
- The firm has written/updated and implemented the following SOPs since the previous inspection.

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- Food Defense Plan
- Customer Complaints
- Corrective actions
- Crisis management
- GMPs
- Pest Control
- Environmental control
- Product testing
- Facility Sanitation
- Receiving and Shipping
- Internal Audits
- Vendor Management
- Recalls
- Management Review
- Non-conforming Product or Equipment
- Rework
- Standard Sanitation Operating Procedure
- Captive Footwear
- Calibration
- Allergen Management
- Temperature Monitoring
- Material Storage and Segregation
- Traceability
- sSOPs for Equipment
- Training
- Listeria Testing
- (b)(4) Swabbing

EXHIBITS COLLECTED

1. A Bill of Lading, dated 12/15/2017, that documents a shipment of finished hummus from the firm's (b)(4) in (b)(4) to a warehouse in (b)(4). (Two pages)
2. Ingredient Hazard Analysis (Twelve pages)
3. Process Hazard Analysis (Eight pages)
4. Process flow diagram (One page)
5. Floor plan (One page)
6. Corrective Action Forms for environmental testing (Fifteen pages)

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7. Corrective action flow diagram for environmental control (One pages)
8. Product Release Matrix (Three pages)

ATTACHMENTS

1. FDA 482, "NOTICE OF INSPECTION", dated 12/18/2017, issued to Christopher F. Penny, Chief Operating Officer, Cava Foods, LLC, located at 13250 Mid Atlantic Blvd., Laurel, Maryland, 20708 (Three pages)

X Jessica D.
Nanini -S



Digitally signed by Jessica
D. Nanini -S
Date: 2024.08.20 08:58:51
-04'00'
