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SUMMARY (VAM & JDW)

This comprehensive 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 17 Work Plan, FACTS Assignment ID 11717490, and eNspect Operation ID 54853. This was a full Preventive Controls inspection directed by CFSAN.

The previous inspection was conducted under FDA Contract by the Maryland Department of Health and Mental Hygiene on 5/4/2015 and classified as VAI. The following observations were documented on the State's Inspection report:

1. Inadequate sanitation, sanitation procedures, and/or sanitation monitoring: Old food spatter on the ceiling and beams above the product filler
2. Utensils are not constructed or maintained as to provide for adequate cleaning or preclude adulteration of foods: The (b)(4) sieves used for citric acid are damaged and in a state of disrepair.
3. Ingredients, work in progress, and finished foods are not handled in a way that protects against contamination:
    a. The (b)(4) unit for the finished product (b)(4) cooler is leaking.
    b. Sieves used for citric acid are stored unprotected in the loading dock area.
    c. In a (b)(4) gasoline cans are stored next to buckets used to handle foods.
    d. Bottles of sanitizer spray are stored on a shelf with ingredients.
    e. Ceiling panel and light fixture falling down from ceiling in loading dock area
4. Ineffective measures to exclude and/or control pests:
    a. The overhead dock door servicing the final product loading dock is not rodent proof.
    b. There are holes large enough to allow entry of pests in a wall at the receiving dock.
5. The plant and facilities are not constructed and maintained in such a manner that floors walls and ceilings may be adequately cleaned: The finish of the concrete floor is damaged and worn throughout processing area.
6. Sanitizing agents shall be adequate and safe under conditions of use: No test strips for verifying concentration of sanitizer solution.
7. (b) (3) (A) .

Since the previous FDA State Contract inspection, the firm has relocated from Rockville, MD, to a new building in Laurel, MD. Observations one through seven were verified as corrected during the current PC Inspection.

The current inspection was conducted by FDA 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. The firm also ships some finished product 8oz hummus and all of its salad dressing dips to be (b)(4)

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.

During the current inspection an FDA-483, "INSPECTIONAL OBSERVATIONS" was not issued. Six items were discussed with management. Items 2, 4, 6, and 7 were corrected on-the-spot during the current inspection. Corrections to items 5 and 8 will be completed within two weeks, but were not 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 (b)(4) 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 (b)(4) 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.

(b) (3) (A) .

A reconciliation exam was performed on Lot # (b)(4) Organic Chickpeas. No discrepancies were identified.

Sample INV 941127 was collected, consisting of 119 environmental swabs to be analyzed for listeria monocytogenes. The sample was provided to Investigators at no cost.

No refusals were encountered.

ADMINISTRATIVE DATA (VAM)

Inspected firm:	Cava Foods LLC
Location:	13250 Mid Atlantic Blvd Laurel, MD 20708
Phone:	301-984-1680
FAX:	301-984-1681
Mailing address:	13250 Mid Atlantic Blvd Laurel, MD 20708
Dates of inspection:	3/20/2017-3/23/2017
Days in the facility:	4
Participants:	**Jessica D Weber, Investigator, BLT-DO** **Valeria A Moore, Investigator, BLT-DO** **Mohamad A Chahine, Investigator, BLT-DO** **Karen A Spencer, Investigator, BLT-DO** **Sherry Donovan-Morris, Regional Env. Health Spec., MDHMH**

On 3/20/2017 FDA Investigators Jessica D. Webber, Karen A. Spencer, Mohamad A. Chahine, Valeria A. Moore and MDHMH Sanitarian, Sherry A. Donovan-Morris presented credentials and issued an FDA-482, "NOTICE OF INSPECTION" (**Attachment 2**) to Ms. Karen E. Morales-Jones,

Production Packing Manager of Cava Foods, LLC, who stated she was the most responsible individual present at the firm. Ms. Morales-Jones contacted Jason R. Huck, General Manager, before accompanied Investigators on a walkthrough of the facility. Upon Mr. Huck's arrival to the firm, an FDA-482, "NOTICE OF INSPECTION" (**Attachment 3**) was reissued to Mr. Jason R. Huck, General Manager of Cava Foods, LLC.

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

The firm was provided the FDA handout for Assessment and Reinspection and Recall User Fees, the Reportable Food Registry information sheet. The firm was also provided Final Rule Preventive Control Fact Sheets for Human and Animal Foods, Third Party Certification, Sanitary Transportation and Supplier Verification.

At the conclusion of the inspection no FDA-483, "INSPECTIONAL OBESRVATIONS" was issued. An FDA-463a, "AFFIDAVIT" (**Attachment 1**) linking interstate documents and environmental swabs was signed by Mr. Jason R. Huck, General Manager.

An FDA-484, "RECEIPT FOR SAMPLES" (**Attachment 4**) was issued to and signed by Mr. Jason R. Huck, General Manager for the environmental samples.

HISTORY (VAM)

Cava Foods, LLC, is a manufacturer of ready to eat hummus and dipping sauces. Cava Foods, LLC was incorporated in the state of Maryland in 2008. In 2014, Potomac Fine Foods, located at Nebel Street in Rockville, MD was purchased by Cava Group, Inc. and now operates as Cava Foods, LLC. Cava Foods, LLC relocated from Nebel Street in Rockville, MD to Mid Atlantic Blvd in Laurel, MD in October of 2016.

Cava Group, Inc. is the parent corporation for Cava Foods, LLC and Cava Grills, LLC, which employs (b)(4) individuals. Management stated Cava Grills are not franchised establishments and Cava Group, Inc. is owner of both Cava Foods, LLC and Cava Grills, LLC.

There is an additional location of Cava Foods, LLC located in Los Angeles, California. Management stated they are in the process of (b)(4)

The corporate headquarters for Cava Foods, LLC is located at 702 H St NW Washington, DC 20002.

Cava Foods, LLC is classified as an FDA Establishment size (b)(4). The new facility's production area is approximately (b)(4) square feet. The complete space contains offices and conference rooms, a demonstration kitchen, ambient storage, prep kitchen, production and packaging room, equipment

wash room, and (b)(4) coolers, (b)(4) . A plant diagram was obtained (**Exhibit 1**).

Normal hours of operation are (b)(4) .

Management stated the firm has not been involved in any recalls since the previous inspection. The firm has no regulatory history with the FDA. (b) (3) (A) .

Official post inspectional correspondence and FMD-145 letter should be addressed to:
Cava Foods, LLC
Mr. Jason R. Huck, General Manager
13250 Mid Atlantic Blvd
Laurel, MD 20708

INTERSTATE (I.S.) COMMERCE (VAM & JDW)

Approximately (b)(4) of the firm's finished products are distributed into interstate commerce. (b)(4) of products are sold wholesale. (b)(4) for (b)(4) Order Number (b)(4) and Cava PO number (b)(4) documenting the shipment of (b)(4)) of Organic Chick Peas (b)(4) product (b)(4) , for a total of (b)(4) cases of product. These products were shipped under seal (b)(4) on 3/6/2017 from (b)(4) to Cava Foods MD 13250 Mid Atlantic Blvd Laurel, MD 20708 (240) 350-8813. (**Exhibit 2**)

(b)(4) "Certificate of Analysis" dated 3/7/2017, for Cava Purchase Order number (b)(4) (**Exhibit 3**) and Product Specification (**Exhibit 4**) sheet were provided.

Cava Purchase Order # (b)(4) dated 3/2/2017 documents the purchase of (b)(4) pallets of "Chickpeas- Organic" with an expected delivery of 3/9/2017 (**Exhibit 5**).

Cava Purchase Receipt Reception no.: (b)(4) dated 3/7/2017 documents the receipt of "Chickpeas-Organic" from purchase order (b)(4) . Cava applied its own lot number to this received product (b)(4) -301 (**Exhibit 6**)

Finished product is sent to (b)(4) to be (b)(4) (**Exhibit 7**). A (b)(4) BOL (**Exhibit 8**), and associated safety inspection report (**Exhibit 9**) were also collected. In the future, Mr. Huck stated that the firm is going to use (b)(4)

An affidavit was issued and signed by Mr. Jason R. Huck, General Manager, to tie interstate documents together (**Attachment 1**).

Top Three Vendors		
Vendor	**Location**	**Product(s)**
(b)(4)		Chickpeas
(b)(4)		All produce
(b)(4)		Tahini sauce

Top Three Customers		
Vendor	**Location**	**Product(s)**
(b)(4)		All varieties of hummus
(b)(4)		All varieties of hummus
(b)(4)		All varieties of hummus

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED) (VAM)

Cava Foods, LLC, is a manufacturer of ready to eat hummus and dipping sauces. Varieties of hummus include: Crazy Feta, Spicy Hummus, Traditional Hummus and Greek Yogurt Hummus. Hummus is packaged in 8oz and 16 oz containers. The firm currently produces four dipping sauces in 9oz containers, Green Harissa Sauce, Lemon Tahini Sauce, Spicy Turmeric Sauce and Yogurt Dill Sauce. A full product list was obtained (**Exhibit 10**). Labels for Eggplant Dip, Traditional Hummus, and Tzatziki, were collected and appear to be in compliance (**Exhibit 12**).

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED (VAM)

A local organizational chart was obtained (**Exhibit 11**).

During the current inspection an FDA-482, "NOTICE OF INSPECTION" (**Attachment 2**) to Ms. Karen E. Morales-Jones, Production Packing Manager of Cava Foods, LLC, who stated she was the most responsible individual present at the firm. Ms. Morales-Jones contacted Jason R. Huck, General Manager, before accompanied Investigators on a walkthrough of the facility. Upon Mr. Huck's arrival to the firm, an FDA-482, "NOTICE OF INSPECTION" (**Attachment 3**) was reissued to Mr. Jason R. Huck, General Manager of Cava Foods, LLC. Both FDA-463a, "AFFIDVIT" and

FDA-484, "RECEIPT FOR SAMPLES" were signed and issued to Mr. Jason R. Huck at the conclusion of the inspection.

Ms. Karen E. Morales-Jones, Production Manager, was issued the first FDA-482, "NOTICE OF INSPECTION" as she was the most responsible individual present at the firm. Ms. Morales-Jones accompanied the investigators the initial walk through of the firm. Ms. Morales-Jones stated she is responsible for overseeing the production of hummus at the firm. Once Mr. Huck arrived, Ms. Morales-Jones did not participate in the rest of 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) after (b)(4) sanitation 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.

FIRM'S TRAINING PROGRAM (VAM)

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 (JDW)

Cava Foods, LLC continues to operate as a manufacturer of multiple flavors of hummus, eggplant and roasted red pepper dip, tzatziki, spiced feta cheese, and harissa.

The firm consists of (b)(4) coolers (b)(4)), a prep room (kitchen), a dish washing room, a production and packaging area, dry storage and loading dock area, and offices.

The firm's equipment consists of in part, (b)(4) mixers, (b)(4) mixers (removed the week of the inspection during floor resurfacing), (b)(4) , (b)(4) mixers, (b)(4) and (b)(4) with ovens, a stove, sinks, and various preparation tools and surfaces.

(b)(4) Mr. Huck stated the firm produces about (b)(4) bags and (b)(4) cups. Of the cup-packaged product, approximately (b)(4) of it is (b)(4) at (b)(4) . I reviewed a processing record from one of these batches and observed the critical limit is at least (b)(4) for at least (b)(4) seconds.

During the inspection, I chose three refrigerated products to cover: traditional hummus, which is the firm's highest volume product; tzatziki because it contains dairy; and eggplant and roasted red pepper dip because it is unique and also contains dairy.

Ingredient Hazard Analysis & Supplier Approval (JDW)

The firm has not conducted an ingredient hazard analysis (**see the "GENERAL DISCUSSION WITH MANAGEMENT" section of this report, Item #1 for more information**).

Using the "Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry Draft Guidance", dated August 2016, I conducted an ingredient hazard analysis on the ingredients in Traditional Hummus, Tzatziki, and Eggplant and Roasted Red Pepper dip.

Traditional Hummus (label **Exhibit X**, product specification **Exhibit X**)

Ingredient	Biological Hazard	Chemical Hazard	Requires a PC?
Shelf stable, cooked, organic chickpeas in water	None	None	No, firm receives bags of chickpeas that have received a 12D LACF process.
Ice	None	None	No – (b)(4) water
Seasame tahini	*Salmonella spp.*	Mycotoxins/Natural Toxins	Yes
Lemon juice	None	None	No
Raw peeled garlic	pathogenic *E. coli*, *Salmonella spp.*, *L. monocytogenes*, *Shigella spp.*, *S.aureus*, *Giardia lamblia*	Pesticides	Yes
Citric Acid	None	None	No
Salt	None	None	No

Tzatziki (label **Exhibit X**, product specification **Exhibit X**)

Ingredient	Biological Hazard	Chemical Hazard	Requires a PC?
Refrigerated Greek yogurt	*Salmonella spp.*	Mycotoxins/Natural Toxins	Yes – also allergen
Raw cucumber	pathogenic *E. coli*, *Salmonella spp.*, *L. monocytogenes*, *Shigella spp.*, *S.aureus*, *Giardia lamblia*	Pesticides	Yes
Raw fresh dill	pathogenic *E. coli*, *Salmonella spp.*, *L. monocytogenes*, *Shigella spp.*, *S.aureus*, *Giardia lamblia*	Pesticides	Yes
Raw peeled garlic	pathogenic *E. coli*, *Salmonella spp.*, *L. monocytogenes*, *Shigella spp.*, *S.aureus*, *Giardia lamblia*	Pesticides	Yes
Salt	None	None	No

Eggplant and Roasted Red Pepper Dip (label **Exhibit X**, product specification **Exhibit X**)

Ingredient	Biological Hazard	Chemical Hazard	Requires a PC?
Raw eggplant	pathogenic *E. coli*, *Salmonella spp.*, *L. monocytogenes*, *Shigella spp.*, *S.aureus*, *Giardia lamblia*	Pesticides	Yes
Refrigerated yogurt	*Salmonella spp.*	Mycotoxins/Natural Toxins	Yes
Shelf stable, canned, roasted red peppers in water	None	Pesticides	No
Raw fresh parsley	pathogenic *E. coli*, *Salmonella spp.*, *L. monocytogenes*, *Shigella spp.*, *S.aureus*, *Giardia lamblia*	Pesticides	Yes
Raw peeled garlic	pathogenic *E. coli*, *Salmonella spp.*, *L. monocytogenes*, *Shigella spp.*, *S.aureus*, *Giardia lamblia*	Pesticides	Yes
Salt	None	None	No

The firm is in the process of preparing for SQF auditing and has established a supplier control program. There are (b)(4)

Process Hazard Analysis (JDW)

Mr. Boamah provided me with a copy of the firm's process flow chart and process hazard analysis (**Exhibits 13 and 14**). He stated that they have not developed a document that only lists the hazards requiring preventive controls, their monitoring, verification, validation, and record keeping procedures, and their parameter values (**see the "GENERAL DISCUSSION WITH MANAGEMENT" section of this report, Item #1 for more information**).

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" (**see the "GENERAL DISCUSSION WITH MANAGEMENT" section of this report, Item #3 and Exhibit 14 for more information**).

In the steps listed on the flow chart and process hazard analysis, an intermediate refrigerated storage step is missing between the "(b)(4) step and the (b)(4) step (**see the "GENERAL DISCUSSION WITH MANAGEMENT" section of this report, Item #2 and Exhibits 13 and 14 for more information**).

The firm did not consider the ingredient storage, finished product storage, and refrigerated shipping steps as places where hazards could be introduced or controlled (**see the "GENERAL DISCUSSION WITH MANAGEMENT" section of this report, Item #4 and Exhibits 13 and 14 for more information**).

For the firm's other products not listed above, almost all of the ingredients (b)(4) . Sanitizer levels appear to be documented and monitored appropriately.

Items that the firm does not apply a pathogen reduction step to (other than canned items) are yogurt, feta cheese, tahini, lemon juice, spices, citric acid, canola/olive oil, and chia seeds. In the products that require process water, (b)(4) water is used. The firm's processing area is (b)(4) and the mixing process is always (b)(4) per batch.

Additionally, (b)(4) , with a target pH of (b)(4) , depending on the product. The product descriptions in **Exhibit15** document the target pH for each product. I reviewed pH testing records and observed a quality employee performing and documenting a pH test during the current inspection and I had no objectionable observations.

<u>The process is as follows for each item:</u>

Traditional Hummus

(b)(4)

(b)(4)
.

The ingredients are conveyed by an employee to the mixing area (b)(4) and placed into (b)(4) mixers. The mixing and packing area is (b)(4)
(b)(4)

Tzatziki

The process for tzatziki (b)(4) (b)(4)

Eggplant & Roasted Red Pepper Dip

The process for this product is (b)(4) (b)(4)

Because th (b)(4) determine the process hazards. I have included all of the steps that appear to be critical to the process below.

I considered the following hazards for this process:

1. Bacterial pathogen survival of a lethal treatment – hazard requiring a preventive control only applies to (b)(4) product, other products rely on refrigeration.

2. Bacterial growth and/or toxin formation due to lack of time/temperature control – applies at storage and refrigerated distribution steps only. Intermediate processing steps are short.

3. Bacterial growth and/or toxin formation due to reduced oxygen packaging – not likely to occur, product is not ROP.

4. Recontamination due to lack of container integrity – not likely to occur because product is not treated before packaging and relies on refrigeration for control. Product is not cooled in a water bath and is manufactured cold. For (b)(4) product, broken seals are obvious because containers explode during processing and are removed from the lots after processing.

5. Undeclared allergen – incorrect label – hazard requires a preventive control.

6. Undeclared allergens – allergen cross contact – hazard requires a preventive control.

7. Chemical hazards due to misformulation – not reasonably likely occur, all ingredients GRAS.

8. Metal – hazard reasonably likely to occur.

I included all of the steps below that appear to be critical to the process.

Process Control Step	Parameter	Monitoring	Corrective Action	Verification	Records	Comments
Refrigerated Storage, intermediate storage & refrigerated distribution (ingredients and finished product)	(b)(4)	(b)(4) monitored with (b)(4)	Not defined, but given verbally – will segregate, evaluate, and repair. Destroy if necessary	(b)(4) calibration of thermometers Review of records every (b)(4) days.	Temperature monitoring record, (b)(4) verification record	Before inspection, firm was not doing (b)(4) check. Corrected during current inspection.
Apply label (undeclared allergen)	Correct label on product	Verify for (b)(4) run	Not defined, but will complete corrective action form – relabel/destroy and retrain	Review of records every (b) days Test (b)(4)	Filling manufacturing record Testing record	Already being verified and reviewed on filling record by PCQI
Metal	(b)(4) (b)(4) (b)(4)(b)(4) (b)(4)(b)(4)	(b)(4) with standard run (b)(4)	Not defined, but will complete corrective action form – root cause/destroy /recondition/ repair	Calibration of metal detector (b)(4) Review of records (b)(4) (b) days	Calibration record	No metal detection on bag line – already in process of adding, but inspection of equipment during sanitation is recorded
(b)(4) **(only for treated product)**	(b)(4)	(b)(4) monitored during processing	Reject load if didn't meet critical limit, restrict (b)(4) supplier until corrections are made to process.	Review of (b)(4) processing record by PCQI before shipment release	(b)(4) processing record	Reviewed a copy of a processing record – no objections

Allergen Cross Contact (JDW)

The firm manufactures products that contain dairy. Dairy is the only allergen used in the facility. Mr. Boamah stated they use (b)(4) to prevent allergen cross contact. A product containing milk (b)(4) After processing and sanitation, Mr. Boamah uses (b)(4) . Additionally, he stated that (b)(4) . I reviewed documents associated with these verification steps and did not have objectionable observations.

Sanitation Program & Monitoring (JDW)

After each production day, (b)(4) where it is cleaned and sanitized with (b)(4) . The clean in place equipment is cleaned to a (b)(4) (b)(4)

The sanitizer levels (b)(4) , but are verified and documented by Mr. MICHAEL on a "Cleaning Chemical Test" document, which also documents the levels of (b)(4) used to wash produce (**Exhibit 16**).

During the inspection, I observed hose reels attached to the ceiling with nozzles that appear to be high pressure. I asked Mr. Huck how the employees conduct cleaning between batches, or intermediate cleaning. He stated that the employees know they are not allowed to use the hoses for intermediate cleaning and they would not ever be used when product is out in the production area. He stated that they are only used during sanitation. I observed employees cleaning small spills during production with paper towels and water during the current inspection.

Sanitation is monitored on cleaning checklists for each area of the firm. The checklists consist of a list of tasks and spaces for the employees to write the date of the operation and their initials. Mr. Boamah stated that he has been reviewing the documents (b)(4), but not documenting the review. At the beginning of March, before the start of the current inspection, Mr. Boamah re-reviewed the records and stamped them with a date stamp. I stated that it would be best if he added his handwritten initials and made sure to document review of the record no more than (b)(4) after the operation (**see the "GENERAL DISCUSSION WITH MANAGEMENT" section of this report, Item #7 and Exhibits 17 and 18 for more information**).

During the current inspection, I observed employee hygiene practices. Before entry to the manufacturing area, there is a sanitary vestibule. It consists of bathrooms with lockers, hand-washing sinks with paper towels and soap, a hand sanitizer station, smocks, hair nets and beard nets,

gloves, and a boot sanitizer station. The water in the hand washing stations was plumbed with only a hot water connection, which results in the water being hot immediately after activating the flow. We donned firm-issued smocks and followed the firm's employee hygiene procedures. Additionally, in the doorways at several locations inside the production area, there are (b)(4) sanitizer (b)(4) units. I observed that these units were operational during the current inspection and that one was located on the production side of the sanitary vestibule.

During the current inspection, I observed some places on the floor were in disrepair (photo below). The floor consists of a concrete base with an epoxy overlay. Mr. Huck stated that although the facility was newly built and they began operations there in October 2016, the epoxy had already started to separate from the concrete and chip off. When I asked him about the floors, he stated that he knew they were a problem and they have already scheduled a firm to remove the old floors and re-coat them with epoxy. He showed me a sample of the new epoxy, which is a hard, thick surface that is textured for traction. The texture resembles sand on a hard surface. The floor resurfacing started on 3/23/2017 and extended into the weekend.

Environmental Monitoring Verification Program (JDW)

Mr. Boamah explained the firm's environmental monitoring procedure to me. He stated currently they use (b)(4) surfaces for sanitation verification. The swabs used are (b)(4) . The manufacturer's specifications indicate that a failure is (b)(4) . He stated, and I observed, that the firm's monitoring record documents the date, location code, score, comments, initials, and follow-up initials. He stated that (b)(4) and records the scores. He stated that if a score of (b)(4) or more is found, a sanitation employee re-cleans the piece of equipment the next day, records the score, and initials the document. I reviewed examples of the firm's (b)(4) and found only

one location that had a score of (b)(4) which was (b)(4). The document indicated that the location was cleaned and swabbed again, with the outcome after cleaning being zero (**Exhibit 19**).

Mr. Huck and Mr. Boamah explained that before the current inspection, they had already been planning to implement an environmental monitoring program that will include more sites, expand testing to (b)(4), and consist of at least *Listeria spp.* testing. He stated that initially, they are going to test (b)(4) locations (b)(4), and then likely (b)(4) locations (b)(4) if there are no problems. The testing will occur (b)(4) and corrections or corrective actions and retesting with (b)(4) will take place as soon as results of the initial test are available, (b)(4) to retest. Mr. Boamah provided me with a list of sites for the upcoming program, which he stated was going to be implemented as soon as the floors are finished, the testing materials arrive, and the equipment is replaced, which will be approximately two weeks (**Exhibit 20**).

MANUFACTURING CODES (VAM)

(b)(4)

(b)(4)

COMPLAINTS (VAM)

The firm has a written complaint procedure. Management stated that complaints can be received via social media, email, and phone calls. Management stated (b) (6), (b) (7)(C) is responsible for receiving complaints and directing complaints to Mr. Christopher Penny and Mr. Jason Huck to be investigated and resolved. Management stated that no complaints medical in nature have ever been received by the firm. (b) (6), (b) (7)(C) was not present for the inspection. There were no complaints listed for the firm in FACTS.

RECALL PROCEDURES (VAM)

The firm has a written recall procedure. Mr. Michael Boamah, Food Safety and Quality stated he is responsible for initiating recalls. Mr. Boamah stated the firm has never been involved in a recall. The firm has no recalls on file with FDA. Management was provided information on the Reportable Food Registry.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE (VAM)

An FDA-483, "INSPECTIONAL OBSERVATIONS" was not issued during the current inspection.

REFUSALS (VAM)

No refusals were encountered.

RECONCILIATION EXAMINATION (VAM)

A reconciliation exam was performed on Lot # (b)(4) Organic Chickpeas. No discrepancies were identified.

FOOD AND COSMETICS SECURITY & MAINTENANCE OF RECORDS (VAM)

The firm was provided the FDA handout for Assessment and Reinspection and Recall User Fees, the Reportable Food Registry information sheet. The firm was also provided Final Rule Preventive Control Fact Sheets for Human and Animal Foods, Third Party Certification, Sanitary Transportation and Supplier Verification.

GENERAL DISCUSSION WITH MANAGEMENT (JDW)

On 3/23/2017, FDA Investigator Valeria A. Moore, Maryland Regional Environmental Health Specialist Sherry Donovan-Morris, and I, FDA Investigator Jessica D. Weber, held a close out meeting with Mr. Boamah, Food Safety and Quality, and Mr. Jason Huck, General Manager. An FDA 483, "INSPECTIONAL OBSERVATIONS" was not issued to Mr. Huck, but eight items were discussed with Mr. Huck and Mr. Boamah:

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.**

   During the inspection, I discussed how to use the "Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry Draft Guidance", dated August

2016. I provided Mr. Huck with the link to the document on the FDA webpage and showed them what I was doing as I was conducting the ingredient and process hazard analysis for the products I covered. They stated that they understood and would begin work on it immediately. Additionally, I explained what the final food safety plan should look like and directed them to the form in the Guidance.

Despite the lack of an ingredient hazard analysis and food safety plan, the firm's monitoring, verification, and record-keeping practices appear to be sufficient to control the hazards. For the programs that may have required more documentation, such as sanitation verification and metal detection, they already had a plan in place to address the issue and were planning on implementing the plan in the immediate future.

2. **In the steps listed on the flow chart and process hazard analysis, an intermediate refrigerated storage step is missing between the (b)(4) step and the (b)(4) step.**

   During the inspection, I observed that vegetables could be washed, cooked, or otherwise processed and then placed into the cooler overnight for use the next day. Mr. Boamah noted the missing step and added it by hand to his process hazard analysis during the inspection (**Exhibits 13 and 14**).

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"**

   During the inspection, I discussed how to use the "Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry Draft Guidance", dated August 2016. I provided Mr. Huck with the link to the document on the FDA webpage and showed them what I was doing as I was conducting the process hazard analysis for the products I covered. They stated that they understood and would begin work on it immediately (**Exhibits 13 and 14**).

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.**

   I stated that although the steps for these parts of the process were listed in the process hazard analysis, it appeared as though they failed to consider them as steps where hazards could be

introduced or controlled. I explained to Mr. Boamah and Mr. Huck that refrigeration is the only process control for pathogens in a ready to eat product such as hummus. Mr. Boamah stated that he understood and corrected it by hand during the current inspection (**Exhibits 13 and 14**).

5. **There is no metal detector preventive control for products packaged in 12-pound bulk bags, such as hummus and crazy feta.**

Mr. Huck stated that they already had a metal detector on order for the bag line and it should arrive and be operational within two weeks. Mr. Boamah stated that during sanitation, employees (b)(4) inspect the machinery to look for breakage and wear.

6. (b)(4) **sanitation checks were not verified within** (b)(4) **of the record being created.**

Sanitation is monitored on cleaning checklists for each area of the firm. The checklists consist of a list of tasks and spaces for the employees to write the date of the operation and their initials. Mr. Boamah stated that he has been reviewing the documents (b)(4), but not documenting the review. At the beginning of March, before the start of the current inspection, Mr. Boamah re-reviewed the records and stamped them with a date stamp. I stated that it would be best if he added his handwritten initials and made sure to document review of the record no more than (b)(4) after the operation. He stated that he understood and started initialing the documents during the current inspection (**Exhibits 17 and 18**).

7. **There is no documentation of** (b)(4) **checks of the raw ingredient and finished product storage coolers.**

During the current inspection, I observed that there was no documentation of (b)(4) checks of the coolers to accompany the continuous monitoring of the coolers. I explained to Mr. Boamah that a (b)(4) check ensures that the coolers are working as expected and the data loggers are not providing false readings. He stated that he understood and started checking the coolers and documenting the check (b)(4).

8. **Floors are in disrepair.**

During the current inspection, I observed some places on the floor were in disrepair (photo below). The floor consists of a concrete base with an epoxy overlay. Mr. Huck stated that although the facility was newly built and they began operations there in October 2016, the epoxy had already started to separate from the concrete and chip off. When I asked him about the floors, he stated that he knew they were a problem and they have already scheduled a firm to remove the old floors and re-coat them with epoxy. He showed me a sample of the new epoxy, which is a hard, thick surface that is textured for traction. The texture resembles

sand on a hard surface. The floor resurfacing started on 3/23/2017 and extended into the weekend.

ADDITIONAL INFORMATION (JDW)

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

SAMPLES COLLECTED (VAM)

During the inspection, sample INV 941127 was collected. This sample consisted of 119 environmental swabs to be tested for listeria monocytogenes. An FDA-484, "RECEIPT FOR SAMPLES" was issued at the conclusion of the inspection to Mr. Jason R. Huck.

VOLUNTARY CORRECTIONS (JDW)

Since the previous inspection, the firm has moved from Rockville, Maryland to Laurel, Maryland. All of the observations below were observed to have been corrected.

1. Inadequate sanitation, sanitation procedures, and/or sanitation monitoring: Old food spatter on the ceiling and beams above the product filler
2. Utensils are not constructed or maintained as to provide for adequate cleaning or preclude adulteration of foods: The (b)(4) sieves used for citric acid are damaged and in a state of disrepair.
3. Ingredients, work in progress, and finished foods are not handled in a way that protects against contamination:
    a. The condensate pump servicing the condenser unit for the finished product (b)(4) cooler is leaking.
    b. Sieves used for citric acid are stored unprotected in the loading dock area.
    c. In a (b)(4) gasoline cans are stored next to buckets used to handle foods.
    d. Bottles of sanitizer spray are stored on a shelf with ingredients.
    e. Ceiling panel and light fixture falling down from ceiling in loading dock area
4. Ineffective measures to exclude and/or control pests:
    a. The overhead dock door servicing the final product loading dock is not rodent proof.

b. There are holes large enough to allow entry of pests in a wall at the receiving dock.

5. The plant and facilities are not constructed and maintained in such a manner that floors walls and ceilings may be adequately cleaned: The finish of the concrete floor is damaged and worn throughout processing area.

6. Sanitizing agents shall be adequate and safe under conditions of use: No test strips for verifying concentration of sanitizer solution.

7. (b) (3) (A) .

EXHIBITS COLLECTED (JDW & VAM)

1. Cava Foods, LLC Plant Diagram, 13250 Mid Atlantic Blvd Ste 100 Laurel, MD 20708-1431, no date, 1 page.

2. (b)(4) Bill of Lading for (b)(4) Order Number (b)(4) and Cava PO number (b)(4) documenting the shipment of (b)(4)) of Organic Chick Peas, dated 3/6/2017, 1 page.

3. (b)(4) "Certificate of Analysis" for Cava Purchase Order number (b)(4) for "POUCH-Organic Chick Peas" LOT(s): (b)(4) Manufactured (b)(4) , dated (b)(4) , 1 page.

4. "PRODUCT SPECIFICATION" sheet for "#10 Pouch- Organic Chick Peas", dated 5/15/2015, 1 page.

5. Cava Purchase Order # (b)(4) dated 3/2/2017 documents the purchase of (b)(4) pallets of "Chickpeas- Organic" with an expected delivery of 3/9/2017, 1 page.

6. Cava Purchase Receipt Reception no.: (b)(4) documents the receipt of "Chickpeas-Organic" from purchase order (b)(4) , (b)(4) , 1 page.

7. (b)(4) document for (b)(4) documents the (b)(4) of (b)(4) containers (approximately (b)(4)) of finished product hummus of different varieties, 3/16/2017, 1 page.

8. (b)(4) BOL documents the shipments of (b)(4) cases of finished product from (b)(4) to (b)(4) dated 3(b)(4) 1 page.

9. (b)(4) "CARRIER TRAILER QUALITY & SAFETY INSPECTION REPORT", documenting the carrier of this shipment as (b)(4) the trailer used identified as (b)(4) and shipped under Seal# (b)(4) , dated (b)(4) , 1 page.
10. Product list for Cava Foods, LLC, 3/10/2017, 5 pages.
11. Local organizational chart, no date, 1 page.
12. Labels for Tzatziki, Traditional Hummus, and Eggplant & Roasted Red Pepper Dip, no date, two pages.
13. Process flow chart, dated 3/19/2015, one page.
14. Process hazard analysis, "Food Safety Plan", dated 3/19/2015, six pages.
15. Product descriptions, no date, twelve pages.
16. "Cleaning Chemical Test", dated 11/1/2013, two pages.
17. "Cleaning Checklist EOD", dated 10/12/2016, four pages.
18. "Cleaning Log Sheet Production – Prep and Mixing Area", dated 5/22/2013, revision dated 10/28/2016, three pages.
19. (b)(4) ", no date, three pages.
20. List of sites for future environmental monitoring program, no date, three pages.

ATTACHMENTS (JDW & VAM)

1. Original FDA-464a, "AFFIDAVIT", signed by and issued to Mr. Jason R. Huck, General Manager of Cava Foods, LLC located at 13250 Mid Atlantic Blvd Ste 100 Laurel, MD 20708-1431, dated 3/24/2017, 2 pages.
2. FDA-482, "NOTICE OF INSPECTION" issued to Ms. Karen E. Morales-Jones, Production Packing Manager of Cava Foods, LLC, located at 13250 Mid Atlantic Blvd Ste 100 Laurel, MD 20708-1431, dated 3/20/2017, 3 pages.
3. FDA-482, "NOTICE OF INSPECTION" issued to Mr. Jason R. Huck, General Manager, of Cava Foods, LLC, located at 13250 Mid Atlantic Blvd Ste 100 Laurel, MD 20708-1431, dated 3/20/2017, 3 pages.

4. FDA-484, "RECEIPT OF SAMPLES" signed by and issued to Mr. Jason R. Huck, General Manager of Cava Foods, LLC located at 13250 Mid Atlantic Blvd Ste 100 Laurel, MD 20708-1431, dated 3/24/2017, 2 pages.

X Jessica D. Weber

Signed by: Jessica D. Weber -S

X Valeria A. Moore

Signed by: Valeria A. Moore -S

X Karen A. Spencer

Karen A. Spencer
Investigator
Signed by: Karen A. Spencer -S

X Mohamad A. Chahine

Signed by: Mohamad A. Chahine -S