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SUMMARY

Inspection	
Operation ID and Name	178452: FY21 Non-High Risk

Summary Data	
This is a comprehensive report.	
Inspection Basis	Surveillance

Summary

This inspection of Cava Foods, LLC, a hummus, dips and dressings manufacturer was conducted in accordance with Compliance Program 7303.040, Preventive Controls and Sanitary Human Food Operations, under eNSpect OPID #178452.
The previous inspection conducted 12/18/2017 – 12/19/2017 was classified as NAI. An FDA-483, Inspectional Operations, was not issued, however there were three discussion items presented to the firm.

- Jalapeno slicing blades in a cleaned equipment area were observed with residue adhering to their surfaces.
- Employees were observed on the mixing and filling lines handling the outside and inside (food-contact surfaces) of equipment and utensils without changing gloves.
- 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.

These items were observed to be corrected during the current inspection.

The current inspection revealed the firm continues to operate as a hummus, dips, and dressings manufacturer. The firm manufactures traditional and flavored hummus, harissa, and tzatziki in 8oz and 16oz cups, and in 6-12lbs bags. Their dressings are manufactured in 9oz bottles. On 03/07/2022, Investigator Karen Spencer, National Expert, Brian Yaun and I displayed our credentials and issued an FDA-482, Notice of Inspection, to Mr. Jason Huck, Senior Director of Manufacturing, who identified himself as the most responsible person at the firm. We also displayed our credentials to Mr. Patrick McDonald, Plant Manager, Mrs. Rebecca Pfeil, FSQA Manager, and (b) (6), (b) (7)(C), Quality Assurance Technician. Mrs. Pfeil, Mr. McDonald, and (b) (6), (b) (7)(C) accompanied us throughout the course of my inspection where they provided pertinent information regarding the firm and its operations. Investigator Spencer and National Expert, Yaun, were present during the inspection for Human Food Preventive Control OJE purposes.

During the inspection, we observed the manufacture of Cava brand tzatziki in 8oz and 16oz containers. I reviewed the firm's food safety plan, process validation studies, ingredient and process hazard analyses, batch records, sanitation records, corrective action/nonconformance records, sanitation procedures, allergen controls, complaints, environmental monitoring records and employee training. At the conclusion of the inspection there was no FDA-483, Inspectional

Summary
Observations, was not issued to the firm, however the following discussion items were presented: • The firm does not maintain corrective action records documenting adjustments made for leaker tests performed during production. • The firm does not provide their (b)(4) processor with documentation indicating outgoing product has not been processed to control for biohazards. • The firm does not have verification procedures implemented to ensure labeled lids are applied to the correct product by the (b)(4) processor. (b) (3) (A) There were no refusals encountered, nor were there any samples collected. ALERT food defense, re-inspection fee, RFR and FSMA information was discussed with the firm.

Program Assignment Codes Covered	
Program Assignment Code	**Program Assignment Title**
03040	FOOD CGMP INSPECTIONS
03040F	FULL SCOPE PCHF INSPECTIONS

Summary of Discussion Items Not on FDA Form 483 - Current Inspection		
CFR Number	**Citation Text**	**Correction Status**
21 CFR 117.165(b)	You did not establish adequate written process controls verification procedures.	Not Corrected
21 CFR 117.136(a)(2)(i)	You did not disclose to your customer that your food is not processed to control an identified hazard.	Not Corrected

ADMINISTRATIVE DATA

Administrative Data	
Firm	Cava Foods LLC
Physical Address	
Address Line 1	13250 Mid Atlantic Blvd
City / State / ZIP	Laurel, MD 20708-1431
Phone	350-8813
Fax	301-984-1681
Mailing Address	
Address Line 1	13250 Mid Atlantic Blvd Ste 100
City / State / ZIP	Laurel, MD 20708-1431
Inspection Date(s)	2/7/2022, 2/8/2022, 2/9/2022

FDA Inspection Participants
Participant Name and Title
Brian Yaun, National Expert
Karen Spencer, Investigator

FDA Inspection Participants
Participant Name and Title
Mark Jackson, Investigator

Issued 482 Forms	
On the date(s) below, credentials were presented and a "Form FDA 482, Notice of Inspection" (attached) was issued to the person listed.	
Date Issued	**Issued To**
2/7/2022	Jason Huck, Senior Director of Manufacturing

FDA Credentials Were Displayed to the Following Person(s)	
Person's Name and Title	Jason Huck, Senior Director of Manufacturing
Person's Name and Title	Patrick McDonald, Plant Manager
Person's Name and Title	Rebecca Pfeil, FSQA Manager
Person's Name and Title	(b) (6), (b) (7)(C) Quality Assurance Technician

FDA Correspondence Recipient	
Person's Name and Title	Jason Huck, Senior Director of Manufacturing
Email Address	jason.huck@cava.com
Mailing Address	The same as the firm's mailing address.
Phone Number	(301)490-8623

Guidance Documents Given to the Firm
Guidance documents were issued to Mrs. Rebecca Pfeil, FSQA Manager and Mr. Jason Huck, Senior Director of Manufacturing

HISTORY

Food Firm Registration Status	Current	
Hours of Operation	The firm's normal hours of operations are (b)(4) The firm is not operational on (b)(4) .	
New or Current Firm Legal Name	Cava Foods, LLC	
Legal Status	LLC	The firm operates as an LLC which consists of other subsidiaries which include Cava, Cava Mezze and Zoe's Kitchen restaurants. This is the firm's sole location for manufacturing at the present time. Mr. Huck explained there is a new facility located in Verona, VA that will be operational and used for manufacturing and storage later this year.
State of Incorporation	MD	
Incorporation Date	01/01/2011	

INTERSTATE (I.S.) COMMERCE

Description of Interstate Commerce	The firm introduces (b)(4) of their finished product into interstate commerce. The firm distributes their product on via 3rd-party carrier, (b)(4). It was also reported that the firm distributes finished product to their retail restaurants via (b)(4). These products are shipped to (b)(4)

Product Covered	During the inspection, I covered the manufacture of Cava brand tzatziki dip packaged in 8oz and 16oz CPG cup containers, and 6lbs and 12lbs bags.
Incoming	No
Outgoing	Yes
Sent To	I was provided with a Bill of Lading identified as PO Number: (b)(4) (**Exhibit #4**), documenting the interstate shipment of various Cava product including tzatziki dip, to the firm's contracted (b)(4) facility (b)(4)

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)

The firm manufactures traditional and flavored hummus, eggplant and roasted red pepper dips and also dairy based tzatziki dips. These products are packaged in 8oz and 16oz CPG cups and also 6lbs and 12lbs bags. The firm also manufactures Green Harissa, Lemon Herb Tahini and Spicy Lime Tahini dressings in 9oz bottles. I was provided with a copy of the firm's full product list (**Exhibit #2**), and product labels for Cava Traditional Hummus, Harissa and Tzaztiki products (**Exhibit #3**). The firm's sales are (b)(4) wholesale.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Person #1	
Person's Name and Title	Jason Huck, Senior Director of Manufacturing
Roles and Authorities	It was explained that Mr. Huck has oversight of manufacturing at the facility. He also has oversight of the development of the firm's new manufacturing facility located in Verona, VA. Mr. Huck reports to Christopher Penny, Chief Manufacturing & Supply Chain Officer. Mr. Huck identified himself as the most responsible person at the firm at the time of the inspection.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Most Responsible Person Present, FDA Correspondence Recipient
Email Address	jason.huck@cava.com

Mailing Address	The same as the firm's mailing address.
Phone Number	(301)490-8623
Person #2	
Person's Name and Title	Patrick McDonald, Plant Manager
Roles and Authorities	Mr. McDonald explained he has oversight of staffing and facilities at the firm. He manages various teams and departments which include, production, procurement and inventory, and also logistics. He has three primary direct reports. He has been with the firm for over three years.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection
Person #3	
Person's Name and Title	Rebecca Pfeil, FSQA Manager
Roles and Authorities	Mrs. Pfeil stated she has oversight of FSQA aspects of the firm. She reports to Mr. John Schulz, Director of FSQA. Her duties include managing all regulatory compliance and food safety programs headed by the firm. She also monitors the firm regulatory third-party audits, regulatory enforcement and prerequisite programs. She provides training to new and current employees. She has been with the firm for over two years. Mrs. Pfeil provided me with a copy of the firm's organizational chart (**Exhibit #5**).
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection
Person #4	
Person's Name and Title	(b) (6), (b) (7)(C), Quality Assurance Technician
Roles and Authorities	(b) (6), (b) (7)(C) stated his (b)(4) responsibilities include conducting (b)(4) quality assurance checks during production. He conducts verification checks for the firm's CCPs and makes direct observations of the GMP practices. He also conducts the firm's environmental swabbing (b)(4). (b) (6), (b) (7)(C) also explained he conducts (b)(4), batch record, and pH log reviews. He has been with the firm for eight months.
The following are applicable to this person	FDA Credentials Displayed to This Person, Interviewed, Accompanied During the Inspection

FIRM'S TRAINING PROGRAM

The firm has a formal training program where employees are provided with (b)(4) trainings. Training topics covered in the firm's program include food safety, preventive controls, GMPs, allergen management, food defense/food fraud, pest control, (b)(4), and documentation. I reviewed training records for Mr. (b) (6), (b) (7)(C), Batching Lead. There were no deficiencies noted.

MANUFACTURING/DESIGN OPERATIONS

Process Flow, Operations, and Product Coverage

Cava Foods continues to operate as a traditional and flavored hummus, feta cheese, dips, and dressings manufacturer. The firm has a processing area that consists of (b)(4) product packaging/fill lines, an ingredients cooler, finished product storage cooler and a processing area for allergenic and non-allergenic processing equipment.

Since the last inspection conducted 12/18/2017 – 12/19/2017, the firm has added new processing equipment and replaced the firm's hummus manufacturing equipment. It was also explained that all products at the firm undergo (b)(4) processing, where previously only half of the firm's finished products were (b)(4) processed.

On 02/08/2022, I observed the manufacture of Cava tzatziki dip packaged in 8oz and 16oz CPG cup containers. Below you will find my Ingredient and Process Hazard Analyses and description of the manufacturing operations:
Table Answer_122_1

The firm receives their ingredients from approved suppliers. All ingredients used in the processing of Cava products are accompanied with supplier guarantees and Certificates of Analysis (CoAs). Incoming ingredients are examined by the firms QA team for quality, safety, and verification that it was received by an approved supplier and accompanied with a CoA. This is all managed through the firm's supply-chain procedures

Processing & Process Related Hazard Analysis (Tzatziki)

During the inspection, I followed the manufacturing process for Cava brand tzatziki. I (b)(4) this product due to its high volume of manufacturing, and the presence of allergens (dairy). I was provided with a copy of the firm's process flow diagram (**Exhibit #7**) and process hazard analysis (**Exhibit #1, pages 14 - 23**) to compare with my findings.

The process for tzatziki begins with bringing ingredients which include, Greek yogurt, fresh cucumber, fresh dill, raw peeled garlic, and salt from refrigerated and dry storage (salt) into the prep kitchen area. (b)(4)

(b)(4)

Process Flow, Operations, and Product Coverage

(b)(4)

(b)(4)

Mrs. Pfeil provided me with a copy of the firm's (b)(4) process validation studies for traditional hummus and tzatziki (**Exhibit #6**).

After the observing the manufacturing process of tzatziki, I identified the following hazards:

- Pathogen survival of a lethal treatment: Requires a preventive control at the (b)(4) processing step.
- Bacterial growth/toxin formation due to reduced oxygen packaging: The product is not ROP. Does not require a PC for this processing hazard. Also, the product pH is maintained at (b)(4)
- Allergen Cross-Contact: Requires a preventive control through sanitation, use of dedicated equipment and production scheduling.
- Undeclared Allergens – Labeling: Requires a preventive control at the (b)(4) processing step.

Process Flow, Operations, and Product Coverage

- Bacterial growth/toxin formation due to lack of time/temperature control: Does not require a preventive control due to short processing time and temperature controls on the manufacturing floor.

- Metal Inclusion: Requires a preventive control at the metal detector step

The following includes the firm's tzatziki processing steps which were deemed critical after completing my hazard analysis.

Table Answer_122_2

Allergen Cross Contact

As previously stated, the firm manufactures product which contain dairy. It was explained that the firm utilizes dedicated equipment for allergen products, and production scheduling to prevent allergen cross contact contamination. For example, the firm will manufacture traditional hummus (b)(4) such as tzatziki (b)(4). Mrs. Pfeil also explained the firm conducts (b)(4) allergen (b)(4) for randomly selected allergen contact areas. Upon record review, there were no deficiencies noted. I reviewed the firm's written allergen procedures (**Exhibit #8**) and found no deficiencies.

Sanitation

The firm conducts sanitation procedures (b)(4). Mrs. Pfeil explained the firm has contracted a third-party sanitation company who performs sanitation procedures between the hours of (b)(4) Sanitation is also conducted (b)(4) The firm's third-party sanitation company is tasked with cleaning (b)(4) There were no sanitation deficiencies noted.

Environmental Monitoring

The firm performs (b)(4) environmental monitoring where swabs are collected from food contact and non-food contact surfaces (b)(4). It was explained that in the event the firm receives a positive swab, the site is identified, clean, sanitized, and retested. (b)(4) During the inspection, I observed (b) (6), (b) (7)(C) collected environmental swabs at the following sites:

Process Flow, Operations, and Product Coverage

- Mixing bowls – (b)(4) (interior and base)
- Production floor employee boots
- CPG processing line conveyor
- (b)(4) Tank
- (b)(4)
- Floor drain (b)(4) entrance
- Floor drain (b)(4)

Food Safety Plan Summary

Product #1

Basic Food Information

Product Name	Tzatziki
Product Description with Packaging	Cava brand tzatziki dip packaged in a clear, plastic, CPG cup container with a plastic, heat sealed film and plastic snap on lid, with a black and blue stick on label, with white, black and orange lettering.
Ingredients	Greek Yogurt Raw Peeled Garlic Fresh Cucumber Fresh Dill Salt Citric Acid
Intended Use	Human consumption
Storage and Distribution	Stored and distributed under refrigeration.

Finished Product Hazard Analysis

Process Step	Hazards Requiring Preventive Control	Preventive Control Program
Prep/Wash/Chop Ingredients	Bacterial pathogen survival of a lethal treatment	Process
Prep/Wash/Chop Ingredients	Recontamination with environmental pathogens	Sanitation
Prep/Wash/Chop Ingredients	Undeclared allergens - Incorrect label	Allergen
Prep/Wash/Chop Ingredients	Undeclared allergens - cross-contact	Sanitation
Prep/Wash/Chop Ingredients	Undeclared allergens - cross-contact	Allergen
Prep/Wash/Chop Ingredients	Metal	Process
Assemble/Mix	Bacterial pathogen survival of a lethal treatment	Process
Assemble/Mix	Recontamination with environmental pathogens	Sanitation
Assemble/Mix	Undeclared allergens - Incorrect label	Allergen
Assemble/Mix	Undeclared allergens - cross-contact	Sanitation
Assemble/Mix	Undeclared allergens - cross-contact	Allergen
Assemble/Mix	Metal	Process
Metal Detector	Metal	Process
(b)(4) Processing	Bacterial pathogen survival of a lethal treatment	Process
(b)(4) Processing	Undeclared allergens - Incorrect label	Process

Ingredient Hazard Analysis

Ingredient	Hazards Requiring Preventive Control	Preventive Control Program
Greek Yogurt	Allergens - Milk	Supply Chain
Greek Yogurt	Mycotoxins	Supply Chain

Food Safety Plan Summary		
Fresh Cucumber	E. coli - pathogenic	Supply Chain
Fresh Cucumber	Listeria monocytogenes	Supply Chain
Fresh Cucumber	Salmonella	Supply Chain
Fresh Cucumber	Staphylococcus aureus	Supply Chain
Fresh Cucumber	Giardia duodenalis	Supply Chain
Fresh Dill	E. coli - pathogenic	Supply Chain
Fresh Dill	Listeria monocytogenes	Supply Chain
Fresh Dill	Salmonella	Supply Chain
Fresh Dill	Staphylococcus aureus	Supply Chain
Fresh Dill	Giardia duodenalis	Supply Chain
Raw Peeled Garlic	E. coli - pathogenic	Supply Chain
Raw Peeled Garlic	Listeria monocytogenes	Supply Chain
Raw Peeled Garlic	Salmonella	Supply Chain
Raw Peeled Garlic	Staphylococcus aureus	Supply Chain
Raw Peeled Garlic	Giardia duodenalis	Supply Chain
Comparison with Firm's Hazard Analysis		
All hazards requiring a preventive control were identified by the firm.		

Tables and Figures

Table: Answer_122_1

Ingredient	Potential Biological Hazard	Potential Chemical Hazard	Preventive Control Required
Greek Yogurt	Salmonella	Mycotoxin, Milk Allergen	Biological -None Chemical - Yes
Fresh Cucumber	Pathogenic E. coli, Salmonella, L. mono, S. aureus, Giardia	Pesticides	Biological - None Chemical - None
Fresh Dill	Pathogenic E. coli, Salmonella, L. mono, S. aureus, Giardia	Pesticides	Biological - Yes Chemical - None
Salt	None	None	None
Raw Peeled Garlic	Pathogenic E. coli, L. mono, Salmonella, S. aureus, Giardia	Pesticides	Biological - Yes Chemical - None
Citric Acid	None	None	None

Table: Answer_122_2

Processing Step	Critical Limits	Monitoring	Corrective Action	Verification	Records	Comments
Prep/Wash/Chop Weigh	Exclusion of dirt, stones, plastic, and any other foreign material from fresh produce	(b)(4) by kitchen prep team members for products that include fresh cut produce	Document and ID affected lot and remove foreign materials. Notify QA management	Review Produce Wash Logs by QA within (b) working days	Produce Wash Logs	The firm has had CAPA reports which include foreign material such as plastic which would not be detected w/a metal detector
Assemble/Mix	Product must be at a pH of (b)(4)	The pH will be measured using a (b)(4) by Batching Lead for (b)(4) product batch	Retest, recalibrate pH meter. Place product on hold. Remix if necessary	Review of pH batching log, pH calibration logs (b)(4) working days	pH batching logs, pH calibration logs, Nonconformance logs	
Metal Detector	Exclusion of metal (b)(4)	Metal detector is on and operating correctly.	Stop production and place all product on	Review of production records (b)(4) working days	Metal detector test log Nonconformance	

Tables and Figures

		Conduct various test wand calibrations before and after production by line operators	hold from last successful calibration. Determine root cause.		log	
(b)(4) **Processing/ Labeling**	All products receive (b)(4)	Monitor pressure and time of (b)(4) cycles for every lot of product documented on SCADA reports by QA Manager	Product placed on hold by (b)(4) processor. Perform testing and retesting. Destroy product if non-viable	Review of SCADA reports (b)(4) working days	Pre-shipment records SCADA Reports Nonconformance logs	*See *General Discussion with Management*

RECALL PROCEDURES

There have been no changes to the firm's recall procedure.

ADDITIONAL OBSERVATIONS

Observations Not Listed on FDA Form 483	
Observation	**1**
Citation Text	You did not establish adequate written process controls verification procedures.
Observation Details	Specifically, your firm does not have an established verification procedure to ensure labeled lids are applied to the correct finished product by your (b)(4) processor, (b)(4)
Citation Reference	21 CFR 117.165(b)
Supporting Evidence and Relevance	*Please see General Discussion with Management section of the report.*
Discussion With Management	*Please see General Discussion with Management section of the report.*
Correction Status	Not Corrected
Observation	**2**
Citation Text	You did not disclose to your customer that your food is not processed to control an identified hazard.
Observation Details	Specifically, for outgoing product shipped to your (b)(4) processor, (b)(4) your firm does not provide accompanying documentation disclosing products manufactured by your firm which include, but are not limited to tzatziki and traditional hummus have not been processed to control for biohazards.
Citation Reference	21 CFR 117.136(a)(2)(i)
Supporting Evidence and Relevance	*Please see General Discussion with Management section of the report.*
Discussion With Management	*Please see General Discussion with Management section of the report.*
Correction Status	Not Corrected

REFUSALS

Inspection Refusals
No refusal

There were no refusals encountered.

GENERAL DISCUSSION WITH MANAGEMENT

At the conclusion of the inspection, a closeout meeting was held where Mr. McDonald, Mrs. Pfeil, and (b) (6), (b) (7)(C) were all present. During the closeout meeting, an FDA-483, Inspectional Observations, was not issued, however the following discussion items were presented to the firm:

1. The firm conducts leaker tests to monitor the seal quality of their CPG cups. The firm (b)(4) and performs a (b)(4) test to ensure seal integrity. If leakers are discovered during testing or when the product undergoes (b)(4) processing, the firm documents the findings in their Nonconformance Logs, however this system does not include documentation regarding corrective actions that may have been made. Given the firm's high volume of product produced each day, it was found that there are a fair number of failed leaker tests. As described in the firm's Nonconformance and Corrective Action Program procedures (**Exhibit #9**), a Corrective Action Preventive Action Form is to be created if the root cause of the nonconformance cannot be immediately corrected.

- Mr. McDonald stated leaker tests are not instance specific and that the firm monitors leaker testing to track trends and make adjustment as necessary. He further explained the firm will modify their CAPA program and investigation procedure to include formal reports of improvement and adjustments to the process in the event of negative leaker tests.

2. As previously stated, the firm's products are (b)(4) processed by (b)(4) As product is shipped to the processor, there are stickers placed on plastic totes which identify the product as "Not Processed for Biohazards". It was explained to firm management this is not sufficient per 21 CFR 117.136 (a)(2)(i), where it is required that the firm disclose in accompanying documentation that the food product has not been processed to control a specific hazard.

- Mr. McDonald stated the firm will include the statement "Not Processed for Biohazards" on the Bill of Lading provided to the (b)(4) processor upon receipt of unprocessed product. He stated this will be implemented within the coming days after the close of the inspection.

3. The firm's products receive an (b)(4) process (b)(4) steps. The food products are shipped (b)(4) to the (b)(4) processor, (b)(4) The products are shipped without the container lid which has the principal label of the

product affixed with the ingredient information. The firm has left the responsibility of applying the labeled lid to the correct product to the (b)(4) processor, however there is no verification procedure implemented by Cava to ensure this is done correctly.

- Mr. McDonald stated the firm will implement an verification procedure along with appropriate records that document the labeled lids are placed on the correct product. He said this correction will be implemented within the coming weeks after the close of the inspection.

SAMPLES COLLECTED

No samples were collected.

EXHIBITS COLLECTED

Exhibits		
Exhibit Number	**Description**	**Number of Pages**
1	Copy of Cava Foods, LLC Food Safety Plan	32
2	Copy of Cava Foods full product list	5
3	Product labels	3
4	Copy of Cava Foods Bill of Lading under PO Numer (b)(4)	1
5	Cava Foods organizational chart	1
6	Copy of Cava Foods process validation studies for traditional hummus and tzatziki	4
7	Copy of Cava Foods process flow diagram	1
8	Copy of Cava Foods allergen control procedures	3
9	Copy of Cava Foods Nonconformance/Corrective Action Procedures	3

ATTACHMENTS

Attachments		
Attachment Number	**Description**	**Number of Pages**
1	FDA-482, issued to Mr. Jason Huck, Senior Director of Manufacturing.	3

SIGNATURE

Mark A Jackson
Investigator
Signed By: Mark A. Jackson Jr -S
Date Signed: 03-23-2022 12:43:05

Karen A Spencer
Investigator
Signed By: Karen A. Spencer -S
Date Signed: 03-23-2022 20:49:53

Brian R Yaun
National Expert
Signed By: 1300223928
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