

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	1. DISTRICT OFFICE ADDRESS & PHONE NO. SEA-DO 22215 26 th Ave S.E. Suite 210 Bothell, WA 98021 425-302-0340
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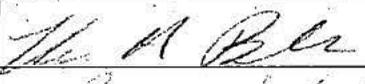
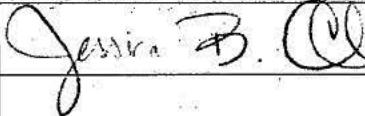
TO	2. NAME AND TITLE OF INDIVIDUAL Jonathan (N.M.E.) Beckley, President	3. DATE 3/14/16
	4. FIRM NAME CRF Frozen Foods, LLC	6. HOUR 8:48 a.m. p.m.
	6. NUMBER AND STREET 1825 Commercial Ave	
	7. CITY AND STATE & ZIP CODE Pasco, WA 99302	8. PHONE NO. & AREA CODE 509-542-0018

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)]¹ and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264]²

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) (Food and Drug Administration Employee(s))	10. TYPE OR PRINT NAME(S) AND TITLE(S) (FDA Employee(s))
 Investigator	Nichole A. Broadbaker, Investigator
 Investigator	Ben Z. Lamb, Investigator
 Investigator	Jessica B. Clark, Investigator

<p>¹ Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:</p> <p>Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information</p>	<p>described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this</p> <p style="text-align: right;">(Continued on Reverse)</p>
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Establishment Inspection Report

CRF Frozen Foods, LLC
Pasco, WA 99301-9533

FEI: **3005098811**
EI Start: 3/14/2016
EI End: 3/17/2016

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SUMMARY (JBC)

This comprehensive inspection of a vegetable processor and repacker was conducted as part of the Seattle District FY16 work plan and in accordance with Compliance Program (CP) 7303.803, Domestic Food Safety.

(b)(3)
(b)(3) This firm has not performed a recall since the previous inspection.

The previous inspection of this firm was conducted by the Washington State Department of Agriculture (WSDA), as an assigned FDA contract inspection and was completed on 09/01/15. This inspection was classified as Voluntary Action Indicated (VAI). The findings listed on the WSDA's Food Establishment Inspection Report included: condensate on piping and the ceiling directly above green bean (b) (4) ice build-up on ceiling/wall juncture in freezer, apparent mold on chlorinated water piping on corn line, black residue on multiple areas of the ceiling in processing rooms, areas of exposed aggregate, plastic used as shielding observed torn and in poor repair, dirt and debris on a white hose on the corn (b) (4), leaking in piping conveying chlorine water on corn line, and two rolling doors were broken. During the current inspection, half of the firm's operations were shut down for the season and some of the above observations

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were unable to be verified as corrected. The following observations have been corrected and were verified during the inspection: no black residue was observed on the ceilings or on water pipes, ice buildup was not observed in the freezer, and the rolling doors have been repaired.

This firm continues to process a variety of fruits and vegetables and repacks vegetables. During this inspection, repacking of frozen corn and peeling of whole onions was observed. A walk through of the firm's production, receiving, and storage areas was conducted as well as a finished product label review. A request to review firm records was made for the following: consumer complaints, recalls, pest control, sanitation, environmental and finished product sample results, interstate shipping documents, receiving documents, and metal detection logs. The firm declined to allow us to review any of the above requested documents. This firm operates (b) (4) a week year round. The firm runs (b) (4) per day for repacking year round, and May – October, the firm runs (b) (4) per day for their processing operations. Office hours are Monday - Friday 8:00 AM to 5:00 PM.

At the conclusion of the current inspection, a Form FDA 483, Inspectional Observations, was issued to firm management for the following: food contact areas throughout several processing lines found with chipped and cracked plastic and areas that are not easily cleanable. Additional observations discussed with firm management included: areas of exposed aggregate throughout the firm, areas of forklift damage throughout the firm walls and doorframes, black plastic used as shielding was observed torn and difficult to clean, blue disposable bags that are designated by the firm to be used for food product were found storing waste instead of using red bags which are designated for waste, a door leading directly to the outside was observed propped open, food contact belt located in close proximity to foot traffic, employees observed walking into restroom with vests on that are also worn during production, and the handwash sink near the onion line was observed not functioning properly. During the close out meeting, firm management committed to correcting the Form FDA 483 observations as well as additional discussion items.

A signed affidavit was obtained covering the firm's purchase of ingredients, production, and distribution of whole peeled onions into interstate commerce. The firm declined to provide interstate documents to include with the affidavit. Environmental sample number INV 885866 consisting of 55 sub samples and INV 886867 consisting of 45 sub samples were collected from the firm's processing areas and submitted for listeria testing, and sample number INV 885868, whole peel onions, was collected and submitted for listeria testing. These samples were not completed prior to the close out of the inspection. At the beginning of the inspection, the firm refused photography and I cited two court cases to the firm President, who continued to refuse. I provided the President's name and contact information to SCSO Schuette, as the firm's Director of Quality Assurance stated he would be the contact for legal matters. Just before conducting environmental swabbing, another attempt was made to take photographs and the firm continued to refuse, citing proprietary concerns and company policy. There were no additional refusals during the inspection. We conducted a follow up on the following Consumer Complaints: #120358, filed on 04/22/11, and #99458, filed on 09/24/09.

Firm management was advised of the legal sanctions available to the FDA if the firm does not correct serious deficiencies. Firm management was also advised that a written response to the Form FDA 483 within 15 business days may impact FDA's determination for the need to follow up. Firm management indicated they

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would be submitting a letter to the Seattle District Office within 15 business days of the close out of the inspection.

Firm management stated that since the previous inspection, there have been no changes to history of business, training program, complaints, and recalls.

ADMINISTRATIVE DATA (JBC)

This was a team inspection conducted by FDA Investigators Jessica B. Clark, Beau R. Lamb, and Nichole A. Broadhacker. Investigator Clark was the lead and prepared most of this report. Investigator Lamb wrote the Interstate Commerce and Jurisdiction sections of this report, presented the Form FDA 463a, Affidavit, and assisted with sample collections. Investigator Broadhacker wrote the Individual Responsibility and Persons Interviewed section of this report, presented the Form FDA 484, Receipt for Samples, and assisted with sample collections. In this report the term "I" refers to Investigator Clark, "we or us" refers to the team. All team members were present throughout the inspection.

Upon arrival to the firm, Ms. Emily J. Camp, Director of Quality Assurance, greeted us and we presented her with our credentials. Ms. Camp escorted us to a conference room where we asked if she was the most responsible individual available, to which she stated the firm's President was the most responsible and Ms. Camp departed to retrieve Mr. Jonathan (NMI) Rodacy, President, who arrived shortly after. We presented our credentials and issued a Form FDA 482, Notice of Inspection, to Mr. Jonathan (NMI) Rodacy, President, who stated he was the most responsible individual over the firm's daily operations. I provided and discussed the Information Sheet – Assessment of Reinspection and Recall Fees by the FDA, version 6, to Mr. Rodacy. In addition, I provided him with the document "What You Need to Know About Registration of Food Facilities", information regarding Biennial Registration, information regarding the Reportable Food Registry (RFR), and Fact Sheet: Proposed Rule for Preventive Controls for Human Food, Fact Sheet: Proposed Rule for Intentional Adulteration, and Fact Sheet: Proposed Rule on Sanitary Transportation of Human and Animal Food. During the course of the inspection, we obtained the information necessary to complete the GMP/PC Data Form.

This firm is also inspected by the WSDA, the WSDA organic division, United States Department of Agriculture (USDA), and is audited through British Retail Consortium (BRC). Ms. Camp stated the USDA is only present while the firm is running product for the school lunch program. The USDA was not present during this inspection.

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Location: 1825 N Commercial Ave
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Phone: 509-542-0018

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FAX:

Mailing address: PO BOX 2508
Pasco, WA 99302-2508

Dates of inspection: 3/14/2016-3/17/2016

Days in the facility: 4

Participants: **Jessica B Clark, Investigator**
Nichole A Broadhacker, Investigator
Beau R Lamb, Investigator

HISTORY (JBC)

Ms. Camp stated there have been no changes to the firm's status since the previous inspection. This firm is (b)(3) (b)(3) The firm's fresh cut plant, which is located on the same property, (b)(3) under the same name and address of: 1801 N. Commercial Ave., Pasco, WA 99301. (b)(3) This firm has not performed a recall since the previous inspection. This firm employs approximately (b)(4) personnel between November – May and approximately (b)(4) personnel between May – October.

FMD-145

Please provide a copy of this report to:
Mr. Jonathan (NMI) Rodacy, President
CRF Frozen Foods, LLC
P.O. Box 2508
Pasco, WA 99302

JURISDICTION / INTERSTATE COMMERCE / DISTRIBUTION (BRL & JBC)

The firm is a processor of frozen vegetables and a packaging facility of fruits and vegetables. Ms. Camp stated the firm sells (b)(4) of their product wholesale and (b)(4)% is distributed outside the State of Washington. Ms. Camp stated the firm's raw vegetables are received from farmers throughout Washington and Oregon. The processing onions are purchased from (b)(4) and Ms. Camp provided us with finished product labeling for corn that is destined for export to Japan and Whole Peeled Organic

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Onions for domestic distribution (**Exhibit #1**). She stated the firm bags products under the following brand names: (b) (4) Ms. Camp provided us with information regarding interstate sales (**See Emily J. Camp, Affidavit, Attachment #1**) but did not provide documentation. Approximately ^{(b) (4)}% of the finished product is exported to Canada, Japan, and (b) (4)

Ms. Camp stated the firm arranges for third party companies to distribute finished products. She stated the firm's largest customers are (b) (4)
(b) (4)

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED (NAB)

Jonathan (NMI) Rodacy is the president of CRF Frozen Foods in Pasco Washington and started with the company in September 2015. He stated he is responsible for day to day operations, correcting observations, customer relations, grower relations, employees, business strategies and tactical strategies. Mr. Rodacy also stated he has some say in who is hired and fired from the facility. Mr. Rodacy has (b) (4) employees that report directly to him. Mr. Rodacy was present during the interview portions of the inspection. Mr. Rodacy reports to Mr. Marty Meyers, CEO of Northwest Operations. Official FDA correspondence should be addressed to: Mr. Jonathan (NMI) Rodacy, President, CRF Frozen Foods, LLC, P.O. Box 2508, Pasco, WA 99302.

Ms. Emily J Camp, Director of Quality Assurance, was our primary contact and was present throughout this inspection. She facilitated the inspection by answering questions, arranging for meetings with the president of CRF Frozen Foods, Jonathan Rodacy. Ms. Camp has been with CRF Frozen Foods for five years. She stated she is responsible for food safety, quality, regulatory topics, audits, consumer complaints, and laboratory activities. Ms. Camp reports directly to Mr. Rodacy and has (b) (4)
(b) (4) that report to her. She stated that when in production the number of technicians is increased to (b) (4). Ms. Camp provided us with all of the information contained within this report with the exception of the sanitation schedule.

(b)(6),(b)(7)(C) Safety and Sanitation Manager, stated he has been with CRF Frozen Foods for approximately one year. (b)(6),(b)(7)(C) responsibilities include safety and OSHA audits and compliance, and reporting employee related accidents in the plant. He also takes care of the sanitation department and wash-downs for equipment. (b)(6),(b)(7)(C) has (b) (4) that reports directly to him; while (b)(6),(b)(7)(C) reports directly to John Toms, Plant Manager. (b)(6),(b)(7)(C) was present during the facility walk through and the interview portion after the walk through. (b)(6),(b)(7)(C) provided us with information pertaining to the sanitation schedule.

(b)(4),(b)(6),(b)(7)(C) was previously the firm's (b)(4),(b)(6),(b)(7)(C). During the inspection, he stated he was working for the firm as a consultant and (b)(6),(b)(7)(C). (b)(4),(b)(6),(b)(7)(C) was present for part of the walk through portion of the inspection.

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FIRM'S TRAINING PROGRAM (JBC)

Ms. Camp stated the firm's training plan has not changed since the previous inspection. She stated the training topics include: HACCP, sanitation, GMP's, and allergens. She further explained the training is conducted in both English and Spanish and all employees are required to receive this training. Ms. Camp and (b)(6),(b)(7)(C) are responsible for the firm's training program.

MANUFACTURING / DESIGN OPERATIONS (JBC)

This firm is comprised of processing areas, repacking areas, storage areas, and receiving areas. Ms. Camp stated the firm has added new lines of equipment since the previous inspection, which are consumer pack lines (b) (4) Ms. Camp also stated no new lines of product have been added since the previous inspection.

During this inspection, we observed the firm re-packing frozen corn and top, tailing, and peeling whole onions. The re-packing process and onion peeling process is outlined below.

Re-packing Corn

The process for re-packing frozen corn begins with transferring totes of previously processed and frozen corn kernels from cold storage, located inside the facility, into the processing area. The totes are dumped into a (b) (4) (b) (4) (b) (4) The corn is weighed, bagged, and runs through a metal detector. The bags are then placed into boxes, sealed, palletized, and stored in cold storage until distribution. Ms. Camp provided a process flow chart (**Exhibit #2**) for this process.

Top/Tail/Peel Whole Onions

The onions are brought into the receiving area and travel into the process area (b) (4) (b) (4) Ms. Camp stated this water is (b) (4) and tested for the level of (b) (4) every (b) (4) (b) (4) The water is collected from (b) (4) and is tested for the level of (b) (4) (b) (4) Ms. Camp stated the firm maintains the level (b) (4) using (b) (4) They then exit (b) (4), through the metal detector and into a finished product tote lined with a plastic bag. Once full, the bag is wrapped, taped, labeled and stored cool until distribution. Ms. Camp provided a process flow chart (**Exhibit # 3**) for this process.

Ms. Camp stated the water used at the firm, as well as the sewer, is a municipal system. During operations on the corn packing line and the onion packing line, we observed employees wearing lab coats, vests, hair nets, beard nets (as necessary), and gloves. Prior to entering the consumer pack line area, the firm has a mandatory hand wash station. This station is automated and utilizes (b) (4) hand soap. The machine begins once an employee places their hands inside the separate chambers and the water/soap mixture sprays

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hands for (b)(4) seconds and hands are dried using the air drier. We observed the hand soap levels are displayed on a gauge that is visible during the handwashing process to verify the level of the soap. Prior to entering the pack line area, employees walk through a boot dip which consists of (b)(4) (b)(4) and are stationed inside a mat with a lip. Ms. Camp explained the firm has been testing this boot dip since January 2016. She stated the firm did not have boot dip stations prior to this. These boot dips are located at all entrances leading directly into processing areas.

Ms. Camp stated the firm requires all suppliers to be Global Food Safety Initiative (GFSI) Certified. She stated this includes a supplier audit, and a completion of a CRF Frozen Foods, LLC questionnaire audit form which includes questions regarding the following: HACCP Plan, CCP's, pest control, hold policy, flow charts, allergen statement, quality systems, food safety program, testing protocols, environmental testing programs, and product specification sheets.

MANUFACTURING CODES (JBC)

The firm codes their product with a best by date. During the inspection, the below codes were used on the top/tail/peel onions

649560000100

ORG ONIONS WHOLE PEEL

6059961

03/16/16

- (b) (4)
-
-
-
-

- 03/16/16 = packing date

SANITATION / PEST CONTROL (JBC)

(b)(6),(b)(7)(C) stated the firm's sanitation program has not changed since the previous inspection with the exception of changing the sanitizer to (b)(4) instead of (b)(4) sanitizer. (b)(6),(b)(7)(C) stated the firm increases the strength to (b)(4) when cleaning

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floors and drains. The firm utilizes test strips to check the strength of the sanitizer. Ms. Camp stated the firm's chemical supplier is (b) (4)

ATP swabs are used (b) (4). Ms. Camp stated (b) (4) areas are swabbed and depending on the results, the firm will conduct the sanitizing step. If the results are above (b) (4) which is the pass/fail limit set by the firm, the areas will be re-cleaned and re-swabbed until those areas pass. The firm also utilizes allergen swabs after re-packing two products: bowtie pasta and edamame. Ms. Camp stated these are the two allergen products re-packed by this firm. She also stated that (b) (4) the firm will run a small amount of product after an allergen product has been run, and after the lines have been cleaned and sanitized, and send it to (b) (4) for allergen testing in the finished product.

During the inspection, we requested to review the firm's sanitation logs and Ms. Camp declined.

Pest Control

Ms. Camp stated the firm's pest control program has not changed since the previous inspection. The firm utilizes (b) (4) to monitor their pest control program. (b) (4) visits the firm (b) (4) to monitor the indoor traps and insect lights and (b) (4) for the outside perimeter bait stations. We requested to review the pest control logs and Ms. Camp declined. We did not observe evidence of rodents during the inspection.

MICROBIOLOGICAL TESTING (JBC)

All testing is conducted in house unless otherwise noted. After reviewing the firm's procedures for the testing outlined below, we requested to review the firm's results of the following tests: incoming product tests, environmental swabs, in-process product, finished product, and re-packed product. Ms. Camp stated she did not think she would allow us to review the test results; however, she would verify this with Mr. Rodacy, and she departed. She came back shortly after and stated Mr. Rodacy explained we were to look at "no records" because it is "proprietary information". She also explained that if the firm's customers asked to look at the results, they also would not share this information. She stated the firm is currently revising their environmental and finished product monitoring program; however, the details of the firm's practices during this inspection are outlined below.

Incoming product

Ms. Camp stated the firm requires Certificates of Analysis (COA's) for each shipment of incoming product. The COA's include test results of Listeria and Salmonella. She also stated the CRF Frozen Foods, LLC collects samples of each batch of incoming product for in-specification grading, standard Aerobic Plate Count (APC), generic E-coli, staphylococcus, yeast & molds.

Environmental Swabs

Ms. Camp stated the firm collects environmental swabs (b) (4), in (b) (4) different processing areas (non-food contact) rotating throughout the firm. The environmental swabs are tested for the following: standard

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APC, coliforms, general E-coli, staphylococcus, yeast, and mold. The firm swabs processing areas (food contact) (b) (4) for Listeria spp., E.coli 0157:H7 and Salmonella, which are sent to (b) (4) in (b) (4). I asked Ms. Camp if the firm had received any positive results since the previous inspection and she stated the firm had not; however, in the event of a positive result, the firm would shut down the affected line, re-clean and sanitize, and re-swab the area. (b) (4) tests would have to be negative before the line would be operational. Ms. Camp also stated the firm would set aside the product and conduct an evaluation on the product to determine its disposition.

In-process Product

Ms. Camp stated the firm conducts in-process testing on samples gathered (b) (4) times (b) (4) while processing. The tests conducted are standard APC, yeast, mold, generic E. coli, coliforms, and staphylococcus.

Finished Product

Ms. Camp stated the firm conducts finished product testing per customer request, not on a scheduled basis. These samples are collected throughout a (b) (4) time frame during processing or packaging, and sent to (b) (4). The firm has utilized this outside laboratory to run these samples since 2013. She explained the tests are conducting using “(b) (4)” which analyzes the molecular content of the product sample and can determine pathogen presence in this manner. Ms. Camp stated the firm places the finished product on hold until the test results return. I asked Ms. Camp if the firm had received any positive results since the previous inspection and she stated they had not; however, in the event they receive a positive result, the product in question would be destroyed.

Re-packed Product

Ms. Camp stated re-packed product is tested at (b) (4) and is analyzed for total APC, staphylococcus, generic E. coli and coliforms.

COMPLAINTS (JBC)

Ms. Camp stated the firm’s consumer complaint procedures have not changed since the previous inspection. She further stated there have been no food safety related complaints since the previous inspection. She did state that the firm occasionally receives complaints regarding stems and pods and other quality complaints. We requested to review the firm’s consumer complaints and Ms. Camp declined. There were two consumer complaints (CC) listed in FACTS for this firm. During the inspection, we followed up on the complaints; however, Ms. Camp was not present during the timeframe the complaints were filed and was unable provide specific information for these complaint investigations.

- CC #120358, dated 04/22/11, was filed by a consumer who alleged they found a dead mouse at the bottom of a bag of frozen green beans. Ms. Camp stated she recalled hearing about this complaint

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and the firm installed (b) (4) in 2013 to prevent foreign materials to be integrated with the product.

- CC #99458, filed on 09/24/09, was filed by a consumer who alleged they found a partial rodent at the bottom of a bag of frozen mixed vegetables. Ms. Camp stated she recalled hearing about this complaint and the firm installed (b) (4) in 2013 to prevent foreign materials to be integrated with the product.

RECALL PROCEDURES (JBC)

Ms. Camp stated the firm's recall procedures have not changed since the previous inspection. She further stated the firm conducts mock recalls (b) (4). The firm's previous mock recall was conducted two weeks prior to this inspection. The firm utilizes the production dates and best by dates on products in order to conduct a recall. The firm also documents the amount of cases and where and how much of the product was shipped. We requested to review these records and Ms. Camp declined.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE (JBC)

Observations listed on form FDA 483

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OBSERVATION 1

The materials and workmanship of equipment and utensils does not allow proper cleaning and maintenance.

Specifically,

1. On 03/14/16, we observed a white, plastic shovel with chips and cracks near the scoop end. This shovel was stored near the production line and is used for food contact.
2. On 03/14/16, we observed blue tape being used as a temporary fix to a cracked metal plate located above the (b) (4) for consumer pack line (b) (4). During this inspection, product designated for export was being repacked on this line.
3. On 03/16/16, we observed chipping, cracking, and missing pieces of plastic in the following areas of the onion line, which, during the inspection, was producing organic white peel onions, lot code: 649560000100, 03/16/16.
 - a) The clear plastic shield separating the (b) (4) was found ripped in the middle and broken and cracked on both edges.
 - b) The plastic conveyor belt located between the (b) (4) had pieces of plastic missing from at least five of the legs. The legs come into direct contact with the onions.
 - c) Utility knives used to hand slice undesired pieces off of the onions have etched initials directly on the blades, leaving a rough surface.

Supporting Evidence and Relevance:

1. During the inspection, Ms. Camp verified the white shovel is used during production and used as a food contact surface on a daily basis to scoop product as needed during the re-packing process. We observed chips and cracks on the scoop, leaving areas that are not easily cleanable. There is no kill step in place for pathogens on the finished product after this step.
2. Tape that is not easily cleanable was being used as a temporary fix for the cracked metal plate above the (b) (4) for consumer pack line (b) (4) which is used on a daily basis during the re-packing process. We also observed condensation build up on this area. There is no kill step in place for pathogens on the finished product after this step.
3. The plastic shield, plastic conveyor belt and utility knives leave areas that are not easily cleanable. These are direct food contact surfaces that are used on a daily basis. There is no kill step in place for pathogens on the finished product after this step.

Discussion with Management:

Ms. Camp immediately removed the white shovel and asked the employees to dispose of it. She stated it is not the firm's practice to use the blue tape as a temporary fix and it will be removed immediately. She stated

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the above areas of the onion line would be repaired or replaced and she would ensure the blades of the knives are not etched on. Ms. Camp stated she would also develop a form that employees can submit to management regarding equipment and utensils that are observed frayed, chipped, cracked, etc. to assist in identifying the tools and utensils that need to be replaced. She would institute these corrections by 03/31/16.

SAMPLES COLLECTED (JBC)

The following samples were obtained during this inspection:

- 1) INV 885866, consisting of 55 subs (31 sponges, 24 swabs), collected aseptically on 03/15/16. The samples were collected from the firm's Consumer Pack Line ^{(b) (4)} during re-packing of frozen corn, Use by: 2018.03.15. Samples were analyzed for Listeria
- 2) INV 885867, consisting of 45 subs (24 sponges, 21 swabs), collected aseptically on 03/16/16. The samples were collected from the firm's Onion Line during top/tail/peeling of whole onions, Date Produced: 03/16/16. Samples were analyzed for Listeria.
- 3) INV 885868, consisting of twenty whole onions, collected aseptically on 03/16/16. The samples were collected from the firm's finished product bins, Date Produced: 03/16/16. Samples were analyzed for Listeria.

REFUSALS (JBC)

The firm refused photography during our inspection. At the beginning of the inspection, the firm refused photography and I cited two court cases to the firm President, who continued to refuse. I provided the President's name and contact information to SCSO Schuette, as the firm's Director of Quality Assurance stated he would be the contact for legal matters. Just before conducting environmental swabbing, another attempt was made to take photographs and the firm continued to refuse, citing proprietary concerns and company policy.

GENERAL DISCUSSION WITH MANAGEMENT (JBC)

Ms. Emily J. Camp was present during the close out meeting. The firm's President, Mr. Jonathan (NMI) Rodacy, was out of town during the close out meeting. At the close of the inspection and after the issuance of the Form FDA 483, I advised Ms. Camp of the legal sanctions available to the FDA. I stated, "Conditions listed may after further review by the Agency, be considered to be violations of the Federal Food, Drug & Cosmetic Act or other statutes. Legal sanctions available to the FDA may include seizure, injunction, civil money penalties and prosecutions if establishments do not voluntarily correct serious conditions." I also stated management is encouraged to submit a written response to Seattle District Director, Miriam Burbach, within 15 days of the issuance of the Form FDA 483. Ms. Camp indicated he would be writing a response

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letter noting her planned corrective actions for the observations discussed with her at the close out meeting. Form FDA 483, Inspectional Observations, was issued to Ms. Emily J. Camp, Director of Quality Assurance.

In addition to the Form FDA 483, we also discussed the following items with Ms. Camp:

1. We observed areas of exposed aggregate under the corn line and under the onion line conveyor belt leading to the (b) (4) station, leaving flooring that is not easily cleanable. Ms. Camp stated the firm is aware of these areas and has each area set up for correction on a scheduled basis. Ms. Camp showed us part of the areas that have already been corrected. She stated the firm's plan is to have the corn line repaired by (b) (4) 2016 and the onion line repaired by (b) (4) 2016.
2. We observed areas of forklift damage throughout the firm, near door jambs, as well as a hole approximately 4" x 8" in the cooler. These areas are observed in poor repair. Ms. Camp stated the firm will fix these damaged areas by 03/31/16.
3. We observed sheets of black plastic hanging near Consumer Pack Line (b) (4). Parts of the sheet were observed torn and fixed with tape. We asked Ms. Camp what the sheet is used for and she said the firm utilizes it to separate (b) (4). We explained that these sheets appeared to be difficult to clean and sanitize and could be a source of contamination. Ms. Camp stated the firm has been testing out different styles of this sheeting and she will be looking for (b) (4) that can be easily sanitized as well as anchored to the floor. She stated the firm will be correcting this by 04/17/16.
4. The firm designates blue plastic bags for finished product and red plastic bags for waste. We observed at least two blue plastic bags being used for waste. We explained the potential for cross contamination and Ms. Camp stated she would conduct companywide employee training by 03/31/16 to remind employees not to utilize the blue bags for waste.
5. We observed a pest trap being used to prop open a door in the filter room, which was leading directly to the outside. Additionally, the boiler room door was propped open into the filter room. We explained this allows pest entrance into the firm, and Ms. Camp stated she would include this observation in the employee training, which will be conducted by 03/31/16.
6. At Line (b) (4) we observed a food conveyor belt located approximately three inches above the floor surface. Employees walk along this floor surface, and the metal plate guarding the food conveyor belt is not adequate to protect this food conveyor belt. Ms. Camp stated the firm will find a solution to protect this belt by 04/17/16.
7. We observed at least two employees walking into the restroom wearing vests that are worn in the production areas. We explained the potential cross-contamination concerns with Ms. Camp and she stated she would include this observation in the employee training, which will be conducted by 03/31/16.

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8. The firm's designated hand wash sink for the onion line was not functioning properly during the inspection. There are two sinks available for hand washing and one side worked only once of the several times we attempted to use. When CSO Broadhacker attempted to wash her hands at the second sink, the water would not turn on after several attempts to run the hand near the sensor. She was able to wash her hands; however, we explained to Ms. Camp that this could impede employees from conducting hand washing. She stated throughout the inspection, the maintenance crew reported back to her that the sinks were working properly even though we observed otherwise. She stated she would ensure the hand wash sinks would be repaired by 03/31/16.
9. The firm's kitchen sink located in the employee break room is missing a handle for the hot water and we observed an employee using this sink as a utility sink for a mop. Ms. Camp stated the firm would fix the handle and she would conduct employee training to ensure employees are using their designated utility sink versus the kitchen hand washing sink. The training would be conducted before 03/31/16.
10. We observed the trash receptacle in the production area that was not in operation was located outside and we were unable to throw our paper towels into the trash after conducting hand washing. Ms. Camp stated she would include this observation in the training session to be held before 03/31/16.

ADDITIONAL INFORMATION (JBC)

We documented the following additional information during the inspection for the *Listeria monocytogenes* environmental swabbing details.

1. The firm does not contract out any of their operations.
2. The firm has implemented supplier controls – please see Manufacturing / Design Operations and Microbiological Testing sections for more details.
3. Ms. Camp explained the firm's kill steps for pathogens as: the firm installed (b) (4) for micro reduction and help to reduce bacterial load and is used in the vegetable processing areas. We did not watch this process during the inspection as these areas were not operational. Ms. Camp stated this is not a validated process as the firm is utilizing this to assist in the reduction of microbes. She stated the firm changes (b) (4) at the end of every processing season (November). The firm utilizes (b) (4) for the onions after they have been top/tailed/peeled. The level is between (b) (4) and the levels are checked and documented every (b) (4) through the use of (b) (4). Ms. Camp stated the firm uses (b) (4) (b) (4) for the (b) (4) levels. Ms. Camp stated the firm utilizes the following precautions to prevent cross contamination after processing: the employees utilize hand washing and gloves, impromptu training on employee practices as needed, glass, plastic, and (b) (4) GMP audits, and (b) (4) third party audits.

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4. Ms. Camp explained that employees are trained that they are unable to work in the production areas if they have any of the following symptoms: diarrhea, vomiting, open wounds or a runny nose. If any employees report these symptoms to their manager, they would be directed to work in a different area of the firm that is not involved with processing.

VOLUNTARY CORRECTIONS (JBC)

We verified that the firm has made the following corrections since the previous inspection:

1. We did not observe black residue on the ceilings in any processing or re-packing rooms.
2. Some areas of the exposed aggregate noted on the previous inspection have been repaired.
3. We did not observe ice build upon the ceiling wall juncture in the freezer.
4. The rolling doors are no longer broken.
5. We were unable to verify the below observations as corrected because this area of the firm was shut down for the season:
 - a. Condensate on piping and ceiling directly above green bean (b) (4)
 - b. Mold-like residue on chlorinated water piping on corn line
 - c. Dirt and debris on the white hose on the corn (b) (4)
 - d. Leak in piping conveying chlorinated water on corn line
6. The firm is also installing a barrier wall (b) (4) in order to help eliminate condensation during processing. Ms. Camp also explained this will separate (b) (4) (b) (4)

ATTACHMENTS (JBC)

1. Form FDA 463a, Affidavit
2. Form FDA 482, Notice of Inspection
3. Form FDA 483, Inspectional Observations
4. Form FDA 484, Receipt for Samples

EXHIBITS COLLECTED (JBC)

1. Finished product labeling (3 pages)
2. Process Flow – Repack Polybag Line (b) (4) 1 page)

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3. Process Flow – Onion Peeling (1 page)

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X Jessica B.
Clark -S

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