

Establishment Inspection Report

Sunland, Inc.
Portales, NM 88130

FEI: 100-011-7188
EI Start: 3/9/09
EI End: 3/10/09

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SUMMARY

This inspection of the peanut butter manufacturer was initiated per FACTS Assignment # 1029425 and consumer complaints: 75632 and 75973 (see attachments). The inspection was conducted in accordance with C.P. 7303.803 (Domestic Food Safety Inspection Program). The purpose of this inspection was to follow up on the above consumer complaints, (b) (4)

(b) (4) and to perform an environmental sample collection as part of the GMP inspection. Sunland, Inc. had shipped (b) (4) (b) (4) of raw in-shell peanuts to (b) (4). These peanuts were returned (b) (4) to Sunland, Inc. and were quarantined in a shipping trailer until their potential disposition could be determined.

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The previous inspection was conducted on 10/23-25/07 and was classified as VAI. At the conclusion of that inspection, a six item FDA 483 (Inspectional Observations) was issued to the firm citing the following: 1) failure to manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganism and contamination; 2) failure to take all reasonable precautions to ensure that production procedures did not contribute to contamination from any source; 3) failure to wash and sanitize hands thoroughly in an adequate hand-washing facility before starting work and after each absence from the work station; 4) failure to take effective measures to protect against the contamination of food on the premises by pests; 5) failure to store raw materials in a manner that protects against contamination; and 6) failure to maintain buildings in repair sufficient to prevent food from becoming adulterated. Observations 5 and 6 were verified as corrected during the current inspection. Similar conditions in observations 1, 2, 3, and 4 were cited in the current inspection.

The current inspection focused on the firm's peanut butter manufacturing process and environmental sample collection for Salmonella. Types of records reviewed included: sample test results, environmental test results, roasting temperature logs, training logs, cleaning logs, pest control policies and service provider logs, and production records.

At the conclusion of the current inspection, the firm was issued a five item FDA 483 citing the following: 1) the firm failed to manufacture foods under conditions and controls necessary to minimize the potential of microorganisms and contamination; 2) the firm failed to take all reasonable precautions to ensure that production procedures did not contribute contamination from any source; 3) failure to take all reasonable measures and precautions to ensure personnel cleanliness by utilizing effective hair restraints and ensuring that beard covers were worn in an effective manner; 4) failure to ensure employees washed/sanitized their hands properly when returning from the work station; 5) failure to maintain equipment used to hold food ingredients in a manner that protects them from contamination. See the attachment FDA 483. Citations 1, 2, and 4 were repeat observations. Observations 1a, 2b, 4a and 5a were corrected on-the-spot or during our inspection. For observations 2a, 2c and 3a, Mr. Pierce agreed to work on correcting these items in one month (April 10, 2009). The break down of observations can be read in the objectionable Conditions and Management's Response section.

Two observations were removed from the FDA 483 for the following reasons: 1) After further discussion with Mr. Pierce, there was a misunderstanding, on our parts, regarding the operation of a piece of equipment, and 2) after reading the FDA 483, it was noticed that there was an observation listed twice.

Comments about corrective actions and timeframes are listed under the Objectionable Conditions and Management's Response section.

Observations not listed on the FDA 483 were discussed with management and are outline in this report under the header General Discussion with Management.

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There were no refusals encountered during the course of the current inspection.

One set of environmental swab samples (INV 515841), including 60 sub samples, were collected per the sample assignment # 1032834 for Salmonella analysis.

Post inspectional correspondence, FMD 145, a copy of the EIR should be sent to:

Mr. Jimmie E. Shearer, President/CEO
Sunland, Inc.
P.O. Box 1059
Portales, NM 88130

ADMINISTRATIVE DATA

Inspected firm: Sunland, Inc.
Location: 42953 US Highway 70
Portales, NM 88130
Phone: 575-356-6638
FAX: 575-356-6630
Mailing address: P.O. Box 1059
Portales, NM 88130
Dates of inspection: 3/9/09, 3/10-09
Days in the facility: 2
Participants: Elvin R. Smith, SCSO; Steve C. Madzo, Microbiologist; Larisa E. Pavlick, CSO; Carla R. Hinz, CSO

On 3/9/09, we presented our credentials and issued the FDA 482 (Notice of Inspection) to Jimmie D. Shearer, President and CEO of Sunland, Inc.

On 3/10/09, Mr. Paul W. Newsome II, Executive Vice President, was issued the FDA 483 (Inspectional Observations).

Elvin R. Smith, SCSO; Analyst Steven C. Madzo, Microbiologist; and Larisa E. Pavlick, CSO, accompanied me during the current inspection to aid me in the aseptic sampling process. Unless otherwise noted (with initials), I, CSO Carla R. Hinz, wrote all portions of this report.

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HISTORY

Sunland, Inc. was incorporated in New Mexico in 1988. Their office hours are from 8:00 a. m. to 5:00 p.m., Monday through Friday. (b) (4)

(b) (4)

(b) (4)

The firm does approximately (b) (4) wholesale and (b) (4) retail. They currently have approximately (b) (4) employees; of which (b) (4) are Sunland full time employees, and (b) (4) are Sunland part time employees. The firm has an annual income of approximately (b) (4)

The firm contracts with about (b) (4) peanut growers in (b) (4). The firm uses approximately (b) (4) acres of Valencia Peanuts and (b) (4) acres of Spanish Peanuts per year.

The firm sits on approximately (b) (4) acres of land and operates mainly from two buildings; the Main Plant and the Peanut Butter Plant. The Main Plant is approximately (b) (4) square feet. It houses the main offices, retail store and processing for the peanuts. The Peanut Butter Plant (established in 2004) is approximately (b) (4) square feet, of which (b) (4) of the facility is storage. The rest is peanut butter production area. The firm has (b) (4) offsite storage facilities for raw peanut products. Farm stock is product after USDA grading and before cleaning. The following are the names, locations and products stored in those facilities:

(b) (4)

See Exhibit # 1 for Sunland, Inc. Peanut Flow chart.

INTERSTATE COMMERCE

LP: Sunland has contracts with farmers to grow and harvest peanuts in (b) (4). Approximately (b) (4) farmers are utilized for peanuts.

Jimmie reported to the investigators during our initial interview that (b) (4) of their products are shipped out of New Mexico.

JURISDICTION

Sunland, Inc. processes whole in-shell and shelled peanuts under the Sunland brand name. Some of the products are: roasted Valencia, organic roasted Valencia, raw Valencia, salted Valencia and organic salted Valencia.

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Sunland manufactures peanut butter (old fashioned and traditional), and flavored peanut butter (15-18 flavors). Peanut butters make up ^{(b) (4)} of total production, cashew butter and almond butter ^{(b) (4)} ^{(b) (4)} and repackage tehini butter ^{(b) (4)} Sunland produces and packages finished products utilizing their own brand name as well as products for contract manufacturing customers. Sunland produces and packages under the following brand names: Sunland (which is their own label), Naturally More, ^{(b) (4)} Maranatha, Earth Balance, Natural Value, ^{(b) (4)} Archer Farms, Fresh and Easy, Kirkland, ^{(b) (4)} Heinen, Arrowhead, Harry and David, Trader Joe's, and General Mills.

See Exhibit # 2 for a list of the Peanut Butter Products.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Jimmie D. Shearer, President and CEO, has been with the firm since 1991. He is responsible for the overall functions of the firm. He answered all questions concerning the technical and financial status of the firm. Mr. Shearer exhibited his authority by instructing Mr. Pierce and Mrs. Rector to accompany and assist us during the current inspection. According to the firm's organization chart (see Exhibit # 3), there is one individual that ranks above Mr. Shearer; Mr. Garvin Chandler, Chairman of the Board of Directors.

Mr. Paul Newsom, Executive Vice President, did not participate in the current inspection however, he was present to accept the issued FDA 483. Mr. Newsom is responsible for arranging transportation for all products and overseeing the sales, production and scheduling functions of Sunland, Inc. He reports to Mr. Shearer.

Mrs. Samantha Rector, Quality Control Supervisor, has been with the firm for 10 years. She has been in quality for 4.5 years. Mrs. Rector is responsible for quality checks, organic certificates, all operational plans, kosher books (certificate of origin), the allergen program, safety plans, HACCP training and the HACCP program. She oversees ^{(b) (4)} employees, but does not control a budget. Mrs. Rector accompanied us during the inspection, answered all questions as they relate to quality and provided all requested documents relating to areas she oversees. She reports to Mr. Shearer.

Mr. Weston Pierce, Peanut Butter Plant Manager, has been with the firm for 11 years. He is responsible for running the peanut butter plant. His duties include overseeing raw materials, production and shipping, QC and complaints, and supplying information for recall. Mr. Weston also has the responsibility of making the call to close down the facility for preventive maintenance. He accompanied us during the sample collection and walk-through of the peanut butter facility. He answered all questions and provided all requested documents as they relate to peanut butter production. Mr. Weston was responsible for making on-the-spot corrections to some observations noted during the current inspection. He reports to Mr. Newsom.

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FIRM'S TRAINING PROGRAM

Employees go through a brief new employee training where they learn about the food GMPs and various aspects of the firm's own regulations. Employees also receive (b) (4) GMP training and (b) (4) training. Logs are kept of who has attended what training.

MANUFACTURING/DESIGN OPERATIONS

Sunland has two separate processing facilities at this location: the Main Plant and the Peanut Butter Production Plant. The current inspection was focused on the latter of the two plants and related to (b) (4). Sunland sent (b) (4) totes of peanuts (b) (4) to be cleaned. These peanuts have been returned to Sunland and placed on hold to await further guidance from CFSAN. During this time, (b) (4) totes containing (b) (4) each were sold to (b) (4).

See Exhibit # 4 for the peanut butter flow process flow diagram and Exhibit #5 for the production lines in the peanut butter plant.

(b) (4)



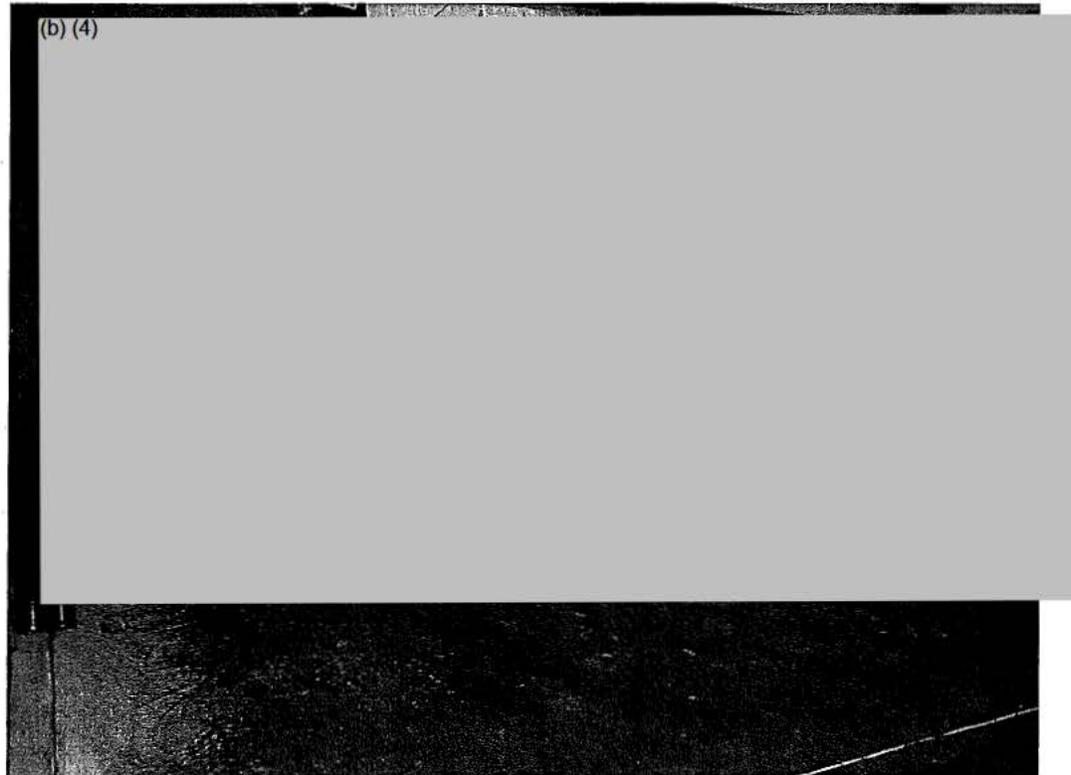
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Peanut Butter Production Plant

Receiving Room-Raw, shelled peanuts were received in (b) (4) ; (totes) weighing (b) (4) each from the Main Plant or from other suppliers via trucks to the receiving room. If peanuts come in from another supplier, they come with an aflatoxin report issued by the USDA, and lot numbers (lot numbers are traced throughout out the production).



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Cleaning Room-totes are fork lifted to the cleaning room (b) (4)
(b) (4)

(b) (4)
(b) (4) From here all peanuts are (b) (4)
(b) (4) outdoor silos. Each silo holds up to (b) (4) lbs of
shelled peanuts. Cleaning of this room consists of (b) (4)

(b) (4)



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Roasting Room (b) (4)

(b) (4)

(b) (4)

The roaster is cleaned (b) (4)

Floors are swept (b) (4)

(b) (4), (b) (6) (b) (7)(C)

Process Room (b) (4)

(b) (4) in the processing room. From the (b) (4) peanuts are sent to (b) (4) lines (b) (4) (b) (4). The (b) (4) line was running the day of inspection, so the following flow will be from the (b) (4) line onto packaging. (b) (4)

Product is pumped to mil (b) (4)

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(b) (4) where the peanut butter undergoes its final grinding and reaches the desired consistency. Product is pumped to a (b) (4) then cooled in the chiller. Peanut butter is pumped through a metal detector and into the fill room.

The metal detector is tested every (b) (4) The shift supervisor runs (b) (4), once the metal is sensed, the product in the line is discarded down a discard shoot. Cleaning in the process room consists of (b) (4) (b) (4) Product is (b) (4) scrapped off of equipment (b) (4) (b) (4)

(b) (4)



Beginning of panorama photo of processing room. The entry door from the roasting room to the grinding room is (b) (4) out of this frame. (b) (4) line is shown in the (b) (4) ingredient weigh stations (b) (4) (b) (4) line).

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(b) (4)



Out of the frame to the left is (b) (4) line. (b) (4) of this photo is the Peanut Hopper followed by Ingredient weigh stations. Ingredients include sugar, salt and (b) (4)

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(b) (4)



Kettles on the (b) (4) wall of the processing room. The ingredient stations are (b) (4) staff shown in this photo.

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Top photo is the Chillers in the processing room. These are located (b) (4) from the kettles and (b) (4) from the ingredient weigh stations. The smaller photo is the last corner of the room with the "(b) (4) line".

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Fill Room-peanut butter is pumped into (b) (4) fill lines in the fill room. Forty pound tubs of Creamy Peanut Butter were being filled on the (b) (4) fill line at the time of inspection. The (b) (4) fill line ends in (b) (4)

The fill line process consists of about (b) (4) employees. (b) (4) (b) (4)
(b) (4)

(b) (4) This process continues until the lot is finished. Once a pallet is full it is placed into the chiller to help set and cool down the finished product. The cooler is held at approximately (b) (4) degrees per Mr. Pierce. Product remains in this room until cooled, and then the shrink-wrapped pallets are placed into the warehouse.

(b) (4)

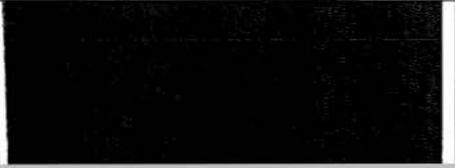
Photo of the filler used for (b) (4) corner of this photo.

A portion of the Capper is shown in the upper right

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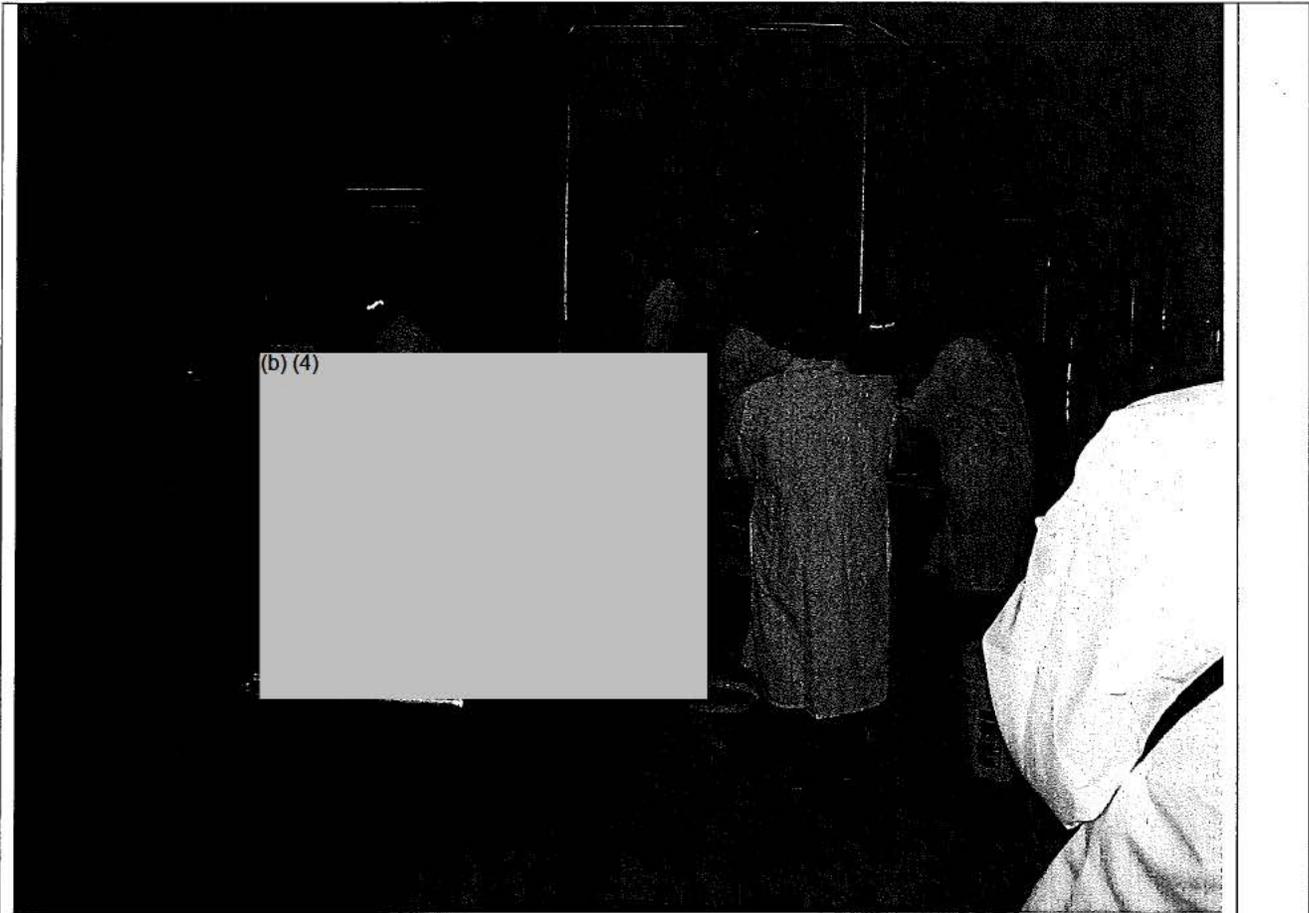
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<p>(b) (6) (b) (7)(C)</p>		
<p>(b) (4)</p>		
<p>Photo of the bulk packaging line. (b) (4) is moving peanut butter from the process room into the buckets. The bucket is shown on a scale.</p>		

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The bulk filling line from the opposite side. The filler used for (b) (4) is located in the (b) (4) however out of this frame. The processing room is (b) (4) shown.

Peanut butter products are packaged in 8 oz to 500 lb containers.

Finished products are shipped via 3rd party carriers such as (b) (4). The firm has forms the loader fills out (Exhibit # 6 trailer/container/vehicle check-off sheet) to document the condition of the delivery vehicle prior to finished products being loaded onto the truck. If the trucks have foul odors, holes in the floor, walls, or roof, insect or rodent infestation, moisture inside the container, or sharp or protruding objects, the truck is rejected.

CLEANING/SANITATION PROCEDURES

According to Mr. Pierce, the firm minimizes the amount of water used to clean throughout their facility. Water is used as part of the (b) (4) on the roaster (b) (4) and in the cleaning room where the (b) (4) line equipment is broken down and washed in the three compartment sink. All other equipment is cleaned with a dry cleaning method to remove the product debris.

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The following information was taken from the firms SOPs on cleaning (Exhibits # 7)

Roasting/Cleaning Room: at the (b) (4) the listed tasks should be completed. The responsible operator will sign when each task is completed. The following items are to be conducted (b) (4)

Roasting Room

(b) (4)

Cleaning Room

(b) (4)

Roaster Wash: the below items are to be done

(b) (4)

Grinding Room: the below items are to be done (b) (4)

(b) (4)

De-aeration Tank: the below items are to be conducted (b) (4)

(b) (4)

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(b) (4)

Packaging Room: items listed here are to be done

(b) (4)

Scrape Surface Heat Exchanger: items listed below are to be done

(b) (4)

Fill Room: no cleaning information was provided specific to the fill room.

SCM

Environmental microbial conditions were evaluated using contact swabs of accumulated debris and product residues in the production environment. The firm has a policy to avoid the use of water in the plant and to rely on sweeping and occasional mopping with a detergent solution. No building vacuum system or portable vacuum system is used to remove debris in the plant. Brooms and mops are not stored in designated equipment lockers and were observed stored in open areas of the production environment. In two areas of the roaster production area a thick layer of discolored peanut fragments, floor dirt and dust were observed. These areas were in a dark corner behind the roaster hoppers and under the compressed air tank adjacent to the roaster oven.

The grinding and filling rooms were observed to have product residues on virtually all the equipment surfaces and in irregularities on the floor surfaces. Peanut butter residues were observed on equipment legs, floor seams and cracks, electric motors, conveyor rollers and behind filling heads. Quality control supervisor Samantha Rector was asked for copies of the cleaning procedure and the cleaning schedule. She replied the cleaning was performed on down time during the (b) (4) production schedule and there was not a fixed cleaning schedule for all the production areas. A

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review of the quality control SOPs for a three month interval showed cleaning was performed on selected equipment such as the roaster and conveyors every ^{(b) (4)} and documented with initial and date. Cleaning and sweeping of the roaster areas was not documented.

MANUFACTURING CODES

The manufacturing codes for the peanut butter consist of a best by date followed by a plant code. The plant code is ^{(b) (4)} and the time is that when the product was filled. For example:

BEST BY
20JAN10
SU 16:21

COMPLAINTS

There were two complaints listed in FACTS prior to the current inspection:

Complaint #75632 was reported by a female complainant in ^{(b) (6), (b) (7)(C)} that consumed Kirkland brand Organic Creamy Peanut Butter (product code 23CCT07/UPC 486730917/ Lot # SU1803/ Best By date 12/29/2008) with crackers on 2/2/09 and 2/6/09. By the afternoon of 2/6/09, she complained of stomach cramps, nausea and diarrhea that were later followed by several bouts of vomiting and a fever. The complainant later complained of extreme tiredness and muscle pains, particularly in the neck. She did not seek medical attention (see attachments)

Complaint #75973 was reported by a male complainant in ^{(b) (6), (b) (7)(C)} that consumed Trader Joes Salted Crunchy Peanut Butter (product code 23CHT07/ and no other product information was given) around January-February 2009. The complainant complained of abdominal cramps, nausea and vomiting and a fever of 106 degrees. Complainant was unable to give exact dates that product was consumed; however, he noted that he had eaten this product once or twice a week. He did not seek medical attention (see attachments).

Mrs. Rector was unaware of the above two complaints. She did provide us with the firm's Customer Concerns list for 2008 (see Exhibit # 8). A review of the customer concerns notes that common complaints received by the firm include consistency complaints on the peanut butter (soupy, runny, dried up, too creamy, lumpy) and taste complaints (funny taste, no flavor (in flavored peanut butters), off taste, and rancid). In most cases, customers were sent replacement product. There was no indication by the firm how they were going to prevent these complaints from occurring in the future.

There were no complains in the log that indicated they were associated with an illness.

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RECALL PROCEDURES

The firm performs mock recalls (b) (4) Mr. Weston Pierce noted that the firm has not had an actual recall.

(b) (6) (b) (4)

(b) (4)

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observation 1

Failure to manufacture foods under conditions and controls necessary to minimize the potential of microorganisms and contamination.

Specifically,

- a) An employee working at the bulk peanut fill line was observed handling the outside of 40 lb finished product buckets and then placing the same gloved fingers on the inside rim of the same buckets as they were being filled with ready-to-eat Creamy Peanut butter. A second employee, on the same fill line, was observed operating the fill switch and then placing part of the same hand inside the 40 lb finished product containers just prior to their being filled with peanut butter. This is a repeat observation from the last inspection.

Reference: 21 CFR 110.80 (b)(2)

Supporting Evidence and Relevance:

The following pictures were taken of the employees with their hands in the buckets.

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(b) (4)



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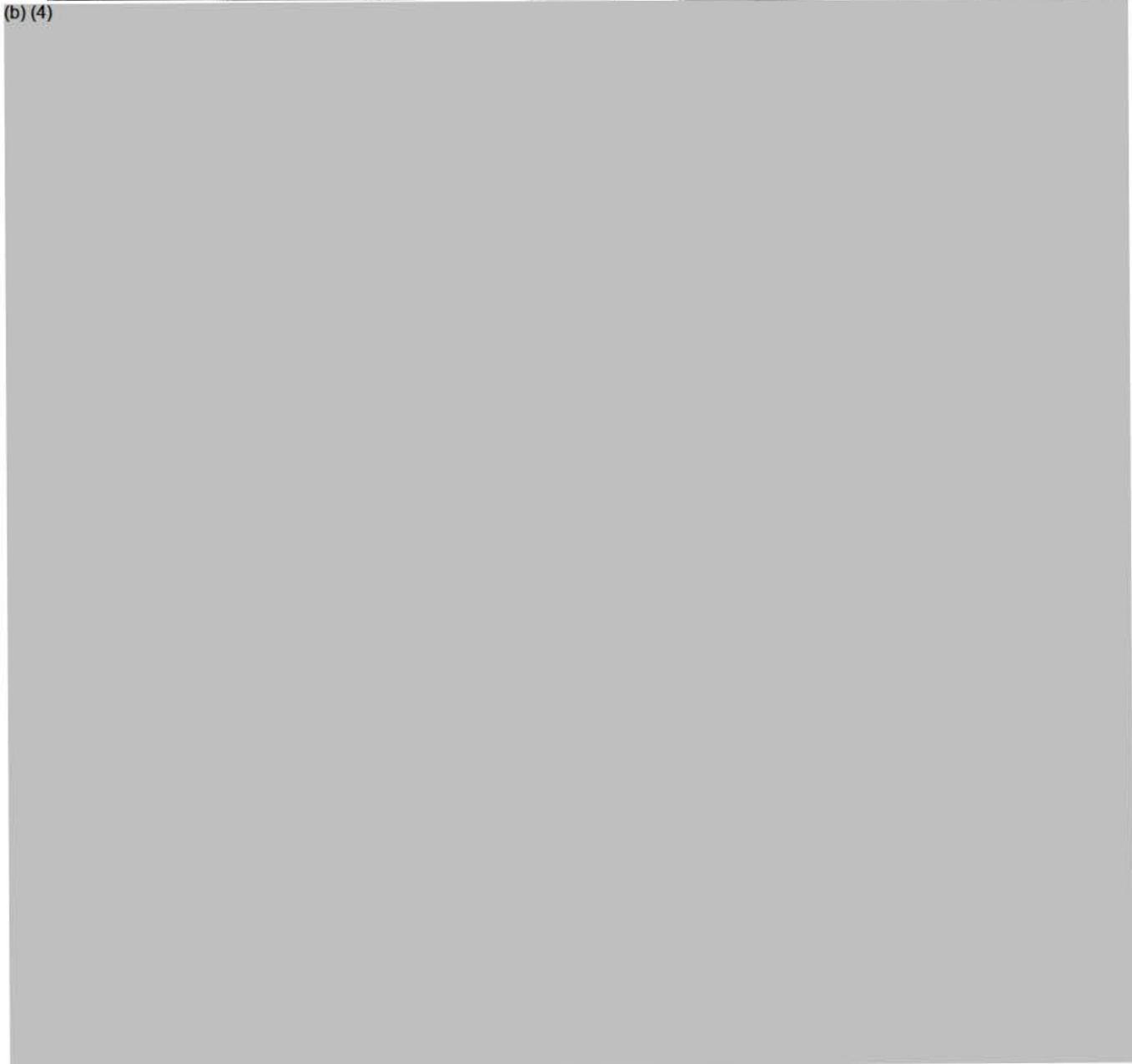
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(b) (4)



Mr. Pierce stated that he would give training to his shift supervisors to ensure that they corrected employees actions that could potential introduce micro-bacteria into the food product.

Observation 2

All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source.

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Specifically,

a) The ^{(b) (4)} leaked peanut butter from the pistons and from gaskets onto the balance tank. A cardboard box (approximately 14"x18"x4") was placed under the leaks to catch most of the peanut butter and it was almost half filled with product. This is a repeat observation from the last inspection.

Reference: 21 CFR 110.40(a)

b) The hand wash sink in the grinder room lacked soap and paper towels. This is a repeat from the last inspection.

Reference: 21 CFR 110.37(e)(2)(3)

c) Product residues were observed on the large ^{(b) (4)} mill (used on the "New Line") as a result of discharging of the pressure relief valve.

Reference: 21 CFR 110.40(a)

~~d) Broken pieces of plastic jar lids were observed in the hopper of the small jar filler line above the area where the conveyor takes the lids to the open jars filled with product.~~

Note: This observation was crossed out on the original FDA 483. The cap sorter on the ^{b4} fill lines was not covered. There were several small broken pieces of caps found around the machine and there was a concern that there was potential for those pieces to get into the finished product, and that being exposed left them open to potential contamination. Mr. Pierce thought it was hardly possible for those pieces to end up in the finished product, however, agreed to consider placing a cover over them to protect them from contamination. After further discussion with Mr. Pierce during the exit interview, it was determined that we had misinterpreted the flow process on this piece of equipment. We reviewed photos taken and agreed that there was minimal health risk present.

Supporting Evidence and Relevance:

Pictures were taken to show the plant at the time of inspection.

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(b) (4)



This is top view of the filler used for **b4** Notice the excess peanut butter which has filled the compartment and collected behind the pistons.

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(b) (4)



This photo is a side view of the filler. Notice the box to the right with a clear plastic bag over it collecting peanut butter dripping out of the compartment shown above.

- a) Mr. Pierce stated that this was an ongoing issue with the (b) (4) because the small gaskets inside of the pistons broke down so quickly. (b) (4)
- b) Mr. Pierce stated that soap and paper towels would be added to the sink in the grinder room immediately.
- c) Mr. Pierce stated that they would look into alternative routes for the discharge pressure relief valve so that it did not land on equipment that was not easy to clean.

Observation 3

Failure to wear beard covers in an effective manner.

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Specifically,

- a) One employee, with a bushy mustache, working on the filling line was not wearing a beard cover. A second employee with a beard and mustache, and working on the same line, was wearing a beard cover that didn't cover his mustache.

Reference: 21 CFR 110.10(6)

Supporting Evidence and Relevance:

There was a discussion with Mr. Pierce, and Mr. Rector on who needed to wear a beard cover. It was explained by Mr. Pierce that it depended on the length of the employee's facial hair. Mrs. Rector explained it could be as long as one inch. There was no consistency between managers. Mr. Pierce had the employee put on a beard cover. Mr. Pierce and Mrs. Rector both agreed to come up with a consistent employee facial hair/beard cover policy and ensure it was enforced.

Observation 4

Employees did not wash/sanitize hands after each absence from the work station.

Specifically,

- a) Three employees were observed entering the finished product fill room and working on the fill line without washing their hands.

Reference: 21 CFR 110.10(3)

Supporting Evidence and Relevance:

Mr. Pierce noted that those employees were immediately pulled aside, after we brought the observation to his attention. He also stated, during the exit interview, that training on proper hand washing was given to all employees of each shift (b) (6)

(b) (6)

There was a discussion with Mr. Pierce of what constituted proper handwashing. His verbal policy, explained to us upon entering the fill room, was that all individuals who enter the fill room must use hand sanitizer. After review of the firms internal GMP's (Exhibit # 9) it is noted under #12 that "Hands should be washed and sanitized before starting work and after each absence from workstation." The interpretation of proper handwashing was discussed with Mr. Pierce in that it includes vigorously rubbing hands together under warm running water with soap and drying with a disposable towel. It was also brought to Mr. Pierce's attention that hand sanitizer is not a substitute for handwashing, however it can be used in addition too. Mr. Pierce agreed that his employees should wash their hands prior to entering the room. Mr. Pierce agreed to train his staff to properly wash hands prior to entering the fill room.

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Observation 5

Failure to maintain equipment used to hold food ingredients in a manner that protects them from contamination.

Specifically,

- a) Brittle, broken and missing gaskets were observed on the under lids of the salt, sugar and b4 bins.

Reference: 21 CFR 110.40(a)

Supporting Evidence and Relevance:

These ingredient bins were located on the weight belt, prior to mill^{(b) (6)}. Mr. Pierce stated that because these gaskets served no purpose, that they would be scraped off of all three lids to the ingredient bins to eliminate the possibility of them breaking off into product.

Photo of b4 located near the b4 Peanut Butter line.
(b) (6)



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Observation 6

~~Lack of effective hand cleaning and sanitizing preparations.~~

~~Specifically,~~

~~There was no soap or sanitizer at the handsink in the grinding room. This was the only hand washing station in the grinding room.~~

~~Note: This observation was crossed out on the original FDA 483 as it was a repeat observation from Observation 2 (b).~~

Discussion with Management:

The following items were discussed in response to the FDA form 483 items as listed above.

1. Mr. Pierce noted that training was given to the employees on proper handling of bulk plastic containers. Mr. Pierce gave this training after the observation was brought to his attention. He noted that this training was discussed with the shift supervisors of all ^{(b) (6)} shifts.
2. a) Mr. Pierce noted that this piece of equipment was broken down during the inspection, completely cleaned and placed back together. He also noted that he is aware of this problem and that it is an equipment design flaw where the gaskets on the pistons get worn down so quickly that it is hard to replace them quick enough. b4
b) Mr. Pierce agreed to have this corrected by the afternoon (3/10/09).
c) Mr. Pierce agreed to look into alternatives for the overflow valve. He did not indicate a time frame.
3. Mr. Pierce agreed that they needed to clarify their internal hair restraint procedure and that employees with facial hair were instructed to wear their beard covers when in the production rooms.
4. Mr. Pierce noted that training was given to the employees on proper hand washing techniques when returning from break. Mr. Pierce gave this training after the observation was brought to his attention. He noted that this training was passed on to shift supervisors of all ^{(b) (6)} shifts.
5. Mr. Pierce noted that the gaskets were to be scraped off, as they provided no function. He noted that this would be done by the end of the day (3/10/09)

REFUSALS

There were no refusals encountered during the current inspection.

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GENERAL DISCUSSION WITH MANAGEMENT

On 3/10/09, a closeout meeting was held with Mr. Paul W. Newsome II, Executive Vice President; Mrs. Samantha Rector, Quality Control Supervisor and Mr. Weston Pierce, Peanut Butter Plant Manager. The 483 was issued to Mr. Newsome in the absence of the President.

We discussed the above listed observations on the FDA 483 and items not listed on the FDA 483. The following items not listed on the FDA 483 were discussed:

1) It was noticed that the rodent traps in the roasting room were placed away from the wall rendering them ineffective. Mr. Pierce noted that the firm had just been sweeping in that room and they had not yet replaced the traps along the walls.

2) There was an open outside door in the machine room (adjacent to the grinding room) that did not exclude pests from entering. Mr. Pierce noted that this door was left open for ventilation. Mr. Pierce was informed that all doors leading to the outside should exclude the entrance of pests. Mr. Pierce agreed to look into what he could do. No time frame for correction was given.

3) The insulation on air ducting above mill^(b)₍₄₎ was torn in the processing/grinding room. This mill had an opening in the lid that did not protect the product should the insulation fall down. Mr. Pierce noted that there was so much grease build up on the insulation that anything that got up there stayed up there. He did note that the firm had been considering removing all ventilation ducting to make it more easily cleanable.

4) There was no conformity among supervisors of how much facial constituted the need of a beard cover. It was explained to Mr. Pierce and Mrs. Rector that if it is their policy that beards/mustaches needed to be covered, then they need to have a clear understanding of that so that it is not confusing to the employees.

5) There were seven uncovered plastic totes of peanut skins, outside on a trailer, that were attracting birds. Birds were observed flying in and out of the totes. Mr. Pierce stated that these skins were

(b) (4)

Mr. Pierce agreed to close the totes so that birds could not get inside of them.

6) In review of the firm's pest management company logs, it was observed that the pest management company had noted that the storage practices in the warehouse provided harborage for pests, and that they needed to maintain a perimeter around the warehouse to prevent such harborage. During the walk through of the warehouse it was noticed that pallets were placed against walls and that the perimeter was not maintained. Mr. Pierce agreed to correct this issue.

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7) Mr. Pierce noted that the overhead piping and insulation was not included in part of the regular cleaning schedule. There was a discussion with Mr. Pierce regarding the importance of keeping all of this piping/insulation free from heavy residue build-up. Mr. Pierce noted that the firm's plan was to remove all the insulation covering the ducting and to add these items to the regular clean schedule.

Observations 1 and 5 were corrected on-the-spot or prior to our closeout meeting with the firm. For observations 2, 3, 4, and 7, the firm agreed to follow-up on these items and to come up with some corrective actions. The managers agreed to follow-up to all issues in writing within one month of the inspection.

E.R.S.

I explained to management that the observations did not represent a final Agency decision regarding the firm's compliance. I explained that after further review by the Agency, the conditions may be considered to be violations of the Food, Drug and Cosmetic Act. I explained that actions may include a warning letter, seizures, injunction, civil money penalties and prosecution are available to FDA if establishments do not voluntarily correct serious conditions. I stated that further actions could be taken by the Agency.

After all discussions, I asked if there were any questions concerning the inspection. After all questions were answered, the inspection was closed.

ADDITIONAL INFORMATION

LP: Sunland utilizes an outside service provider for pest control. The company utilized for pest control is (b) (4). The firm is monitored regularly and logs were available for review. A walk through was conducted of the entire interior perimeter, where possible, and a random check of rodent traps was completed. There were no signs of pests during the inspection. No pests were observed in any of the rodent traps. Most were properly placed against the walls. See Exhibit # 10 for the pest control trap locator map.

The (b) (4) major ingredient suppliers were not covered during this inspection.

SAMPLES COLLECTED

During the inspection 60 environmental swabs were collected aseptically at various locations throughout the peanut butter manufacturing facility under sample # INV 515841 to be analyzed for Salmonella. The following are the locations for each swab sub sample:

Wash Room: sub 1-broom bristles in wash room; sub 2-floor in wash room by inside of door; sub 3-mop bucket in wash room

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Roasting Room: sub 4-NW corner of roasting room-debris on floor; sub 5-SW floor seam of roasting room by roll up door between roasting room and cleaning room; sub 6-inside chart recorder on electrical panel; sub 7-inside electrical panel door labeled "silo" (b) (4) sub 8-debris under east side of roaster on the floor; sub 9-inside of clean out port at east end of roaster; sub 10-floor seam adjacent to roaster South side of roaster (midway down roaster); sub 11-angle iron support for West end (finished product end) of roaster; sub 12-housing for (b) (4) above hopper; sub 13-hopper bracket of motor support above blancher (b) (4) sub 14-inside housing for motor support above blancher (b) (4) sub 15-topside of plastic deflector of blancher conveyer (b) (4) sub 16-floor sample under blancher conveyer (b) (4) sub 17-support under conveyer system under blancher (b) (4) sub 18-inside electrical motor of blancher hopper (b) (4) sub 19-outside of hopper to the augur from the blancher conveyer; sub 20-outside cover to roasting discharge slide; sub 21-floor to door to boarder control center; sub 22-floor under air compressor, North side; sub 23-floor in front of door to grinding room

Grinding Room: sub 24-conveyor cover for (b) (4) peanut line; sub 25-debris under roller of (b) (4) peanut conveyor line; sub 26-torn cover outside of hopper for (b) (4) peanut line; sub 27-floor swab under (b) (4) belt on the small line; sub 28-drain cover in middle of floor; sub 29-debris on overflow valve of the (b) (4) mill; sub 30-outside of motor; sub 31-outside hopper cover to (b) (4) mill; sub 32-floor crack under piping by mill (b) (4) sub 33-outsie panel of monitor (b) (4) sub 340- lid of hopper of power mill (b) (4) floor under piping under power mill (b) (4) sub 34- lid to hopper of power mill (b) (4) sub 35-floor under piping under power mill (b) (4) sub 36-knobs of electrical panel behind power mills (b) (4) sub 37-floor drain under handwash station behind the de-aeration tank; sub 38-debris on motor to vacuum tank (dent in floor); sub 39-crack on floor under pipe to vacuum tank; sub 40-lip of drain cover in the middle of the room; sub 41-floor in front of doorway leading to the mechanical room (grinding room side); sub 42-inside of bracket for motor for granulator; sub 43-wires on metal detector; sub 44-groove under roll up door to warehouse (grinding room side); sub 45-floor seam in front of door to fill room (grinding room side); sub 49-electrical panel labeled "peanut control panel" (b) (4) (sub 49 was out of sequence)

Fill Room: sub 46-actuating handle for fill machine; sub 47-east scale table on fill line; sub 48 broken drain cover adjacent to fill table; sub 49 (see above); sub 50-top of scale read out units; sub 51-edge of recessed drain under (b) (4) compartmetn wash drain; sub 52- rubber foot (on floor) of (b) (4) fill line (currently under repair); sub 53-crevis in doorway of draped door to hall of warehouse (between painted floor and concrete); sub 54-floor crease under West roller door on inside of doorway; sub 55-under filler machine where pistons area; sub 56-metal bracket that holds piston assembly (b) (4) fill line); sub 57-floor under conveyor of (b) (4) fill line; sub 58-conveyor belt prior to filler on (b) (4) fill line; sub 59- top of electrical control panel for (b) (4) fill line; sub 60-top of motor under (b) (4) fill line.

SCM

Mrs. Rector, Quality Control Supervisor, described the collection of microbiology test samples as follows: microbiological test samples are collected every (b) (4) on finished products and every (b) (4) on bulk product. Sampling is based on (b) (4) (b) (4)

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(b) (4)

Products are examined for Salmonella, E. coli, coliforms, total aerobic plate counts, yeast and mold plate counts and aflatoxin. (b) (4)

(b) (4)
(b) (4)

Retain samples are maintained by Ms. Rector (b) (4) depending on the product. See Exhibit # 11 for the firm's Microbiological Sampling for Peanut Butter.

Test records were examined from summary reports and low bacterial and mold counts were found with occasional spikes in aflatoxin. No Salmonella was found in the microbial testing. I asked Ms. Rector what action would be taken if Salmonella was found in the test samples and she said the product would be held in quarantine and discarded.

Products sampled range from 8 oz. jars of finished product up to 500 lb. bulk containers. A single sample jar from the larger size containers may be commingled with smaller size containers to comprise the 15-jar composite for Salmonella testing.

VOLUNTARY CORRECTIONS

Refer to the voluntary corrections listed under the discussion with management headings.

EXHIBITS COLLECTED

- 1) Copy of the firm's Peanut Flow Chart
- 2) Copy of the firm's Peanut Butter Products
- 3) Copy of firm's organization chart
- 4) Copy of firm's peanut butter flow (old and new line-2 pages)
- 5) Copy of firm's production lines in the peanut butter plant (2 pages)
- 6) Copy of firm's trailer/container/vehicle check off sheet
- 7) Copy of firm's cleaning SSOPs (7 pages)
- 8) Copy of firm's Customer Concerns for 2008
- 9) Copy of the firm's Good Manufacturing Practices
- 10) Copy of firm's pest control trap locator map
- 11) Copy of firm's Microbiological Sampling for Peanut Butter

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ATTACHMENTS

FDA 482 (Notice of Inspection)
FDA 483 (Inspectional Observations)
Consumer Complaint # 75632
Consumer Complaint # 75973
Photos of firm and environmental swab locations

Carla R. Hinz

Consumer Safety Officer


Larisa E. Paylick

Consumer Safety Officer

Elvin R. Smith

Supervisory Consumer Safety Officer


for Steve C. Madzo

Microbiologist