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SUMMARY

This inspection of a peanut processor and peanut butter manufacturer was initiated per the Salmonella Sampling Assignment, High Priority, DEP&G# 07-21, ORA Concurrence #2007061901, dated 09/11/07 under FACTS Assignment #851520 (see Attachment #1). The inspection was conducted in accordance with C.P. 7303.803 (Domestic Food Safety Inspection Program).

The previous inspection was conducted on 07/21-22/03 by FDA and was classified as VAI. At the conclusion of that inspection, a five item form FDA 483 (Inspectional Observations) was issued to the firm citing the following: 1) the firm's plumbing constitutes a source of contamination to food; 2) effective measures were not being taken to protect against the contamination of food on the premises by pests; 3) the firm failed to provide adequate screening or other protection against pests; 4) the firm failed to hold rework materials in bulk or in suitable containers so as to protect against

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contamination; and 5) the firm failed to maintain the buildings in repair sufficient to prevent food from becoming adulterated. Observations 1, 3, and 4 were verified as corrected. Similar conditions in observations 2 and 5 were cited in the current inspection.

The current inspection focused on the firm's entire process with emphasis placed on the peanut butter process and salmonella sample collection.

At the conclusion of the current inspection, the firm was issued a six item FDA 483 citing the following: 1) the firm failed to manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination; 2) the firm failed to take reasonable precautions to ensure that production procedures do not contribute contamination from any source; 3) employees were observed not washing and sanitizing hands thoroughly in an adequate hand washing facility before starting work and after each absence from the work station; 4) effective measures were not being taken by the firm to protect against the contamination of food on the premises by pest (this is a repeat observation); 5) the firm failed to store raw materials in a manner that protects against contamination; and 6) the firm failed to maintain buildings in repair sufficient to prevent food from becoming adulterated (this is a repeat observation). Observations not listed on the FDA 483 were discussed with management and are outlined in this report under the header General Discussion with Management.

There were no refusals encountered during the course of the current inspection. One sample (# INV 399193) was collected per the Salmonella Sampling Assignment.

ADMINISTRATIVE DATA

Inspected firm: Sunland, Incorporated
Location: 42593 US Highway 70
Portales, NM 88130-9043
Phone: (505) 356-6638
FAX: (505) 356-6630
Mailing address: P.O. Box 1059
Portales, NM 88130

Dates of inspection: 10/23/2007, 10/24/2007, 10/25/2007
Days in the facility: 3
Participants: Charles D Brown, Investigator
Ricky A. Crouch, Investigator

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On 10/23/07, we presented our credentials, issued the FDA 482 (Notice of Inspection) and 482 Attachment to Mr. Jimmie D. Shearer, President and CEO of Sunland, Inc.

On 10/25/07, Mr. Shearer was issued the FDA 483 (Inspectional Observations).

Analyst Rick A. Crouch, Microbiologist ARL, accompanied me during the current inspection to aid me in the aseptic sampling process. Unless otherwise stated, I, CSO Charles D. Brown, wrote all portions of this report with Mr. Crouch's concurrence.

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)

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, (b) (4) are Sunland part time employees, and (b) (4) Temporary employees. The firm has one position available. The number of employees will decrease during slow production period, which starts around (b) (4). The firm has an annual income of approximately (b) (4).

The firm sits on approximately (b) (4) acres of land and operates mainly from two buildings; the Main Plant and 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 is approximately (b) (4) square feet, of which (b) (4) of the facility is storage. The rest is peanut butter production area. The firm does have an offsite storage facility for product they call farm stock (product after grading and before cleaning). It is located at 2221 Roosevelt Rd #12 in Portales, NM.

The previous inspection was conducted on 07/21-22/03 by FDA and was classified as VAI. At the conclusion of that inspection, a five item form FDA 483 (Inspectional Observations) was issued to the firm citing the following: 1) the firm's plumbing constitutes a source of contamination to food; 2) effective measures were not being taken to protect against the contamination of food on the premises by pests; 3) the firm failed to provide adequate screening or other protection against pests; 4) the firm failed to hold rework materials in bulk or in suitable containers so as to protect against contamination; and 5) the firm failed to maintain the buildings in repair sufficient to prevent food from becoming adulterated. Observations 1, 3, and 4 were verified as corrected. Similar conditions in observations 2 and 5 were cited in the current inspection.

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All post inspectional correspondence should be addressed to:

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

INTERSTATE COMMERCE

Approximately (b) (4) of the firm's raw materials are shipped from outside the state of New Mexico. Three of the firm's top out of state suppliers are:

(b) (4)

Approximately (b) (4) of the firm's finished products are shipped outside the state of New Mexico. Three of the firm's top out of state customers are:

(b) (4)

Out of the (b) (4) interstate commerce, (b) (4) of the sales come from internet sales and less than (b) (4) s sold outside the United States. The firm's internet site is www.sunlandinc.com or www.peanutbetter.com. See **Exhibit #1** for a printout of the firm's website.

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 and flavored peanut butter under the following brand names: Sunland and Peanut Better (which are their own labels), Naturally More, Joseph's, Kirkland (b) (4) Natural Value, Arrowhead Mills, Archer Farms, and Trader Joe's, (which are co-packer's brands).

The firm manufactures almond butter under (b) (4) brand names.

See **Exhibit #2** for product labeling.

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. Mr. Shearer stated that he funded the money for the purchase of Sunland, Inc. He answered all questions concerning the technical and financial status of the firm. Mr. Shearer provided all requested documents as they relate to his position. He exhibited his authority by instructing Mr. Pierce and Ms. 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 Board of Directors.

Mr. Paul Newsom, Executive Vice President, did not participate in the current inspection. He was present during the close of the inspection. Mr. Newsom is responsible for arranging transportation for all products and overseeing the three functions of Sunland, Inc. He reports to Mr. Shearer.

Ms. Samantha Rector, Quality Control Supervisor, has been with the firm for eight years. She has been in quality for the last 3 ½ years. Ms. Rector is responsible for quality check, organic certificate, all operation plans, kosher books (certificate of origin and allergen program), safety plan, HACCP training and HACCP program. She over sees (b) (4) employees, but does not control a budget. Ms. 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 nine 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 preventative 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. 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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Mr. Mark Bruffett, Production Manager, has been with the firm for 13 years. He is responsible for all production in the peanut facility. He oversees cleaning, shelling, fill burns, roasting, packaging, salting and shipping. He has approximately (b) (4) employees working under him. He has the authority to hire and fire employees and is part of the firm's recall team. 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 peanuts. Mr. Bruffett was responsible for making on-the-spot corrections to some observations noted during the current inspection. He reports to Mr. Newsom.

Mr. Derald Hobbs, Maintenance Manager, oversees the firm's maintenance program. He did not take part in the current inspection. He reports to Mr. Newsom.

(b) (6) **Peanut Butter Maintenance**, has been with the firm for six years. He has been in his current position for the last five years. (b) (6) was called into the inspection to explain the conditions of some of the peanut butter processing equipment. He stated that the firm has not conducted any preventative maintenance since September of this year (b) (4). (b) (6) stated that he has been needed in other areas of the firm. He reports to Mr. Hobbs.

A complete and updated organization chart for the firm can be viewed in **Exhibit #3**.

FIRM'S TRAINING PROGRAM

The firm offers their employees (b) (4) GMP training and (b) (4) HACCP training.

MANUFACTURING/DESIGN OPERATIONS

Sunland has two separate processing facilities at this location. In the Main Plant, the building houses the offices and production plant. The production plant in this case is the peanut processing plant. The Main Peanut Warehouse has been converted into the peanut butter production plant. See **Exhibit #4** for a copy of the firm's site diagram of the entire facilities.

Production Plant

The flow diagram for the peanut process is such that peanuts are delivered by trucks on trailer from the farms (See **Exhibit #10**). The trucks are off loaded (b) (4). (b) (4) The peanuts are conveyed to the (b) (4) Cleaner. If necessary, the peanuts are allowed to dry (b) (4).

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(b) (4) USDA would then inspect the peanuts. The peanuts are weighed and dumped. (b) (4)
(b) (4)
(b) (4)
(b) (4) the peanuts are separated, those to be shelled and those that are to remain in-shell.

In-shell peanuts

(b) (4)
(b) (4) The peanuts are checked by Quality Control and inspected by USDA. After inspection, the peanuts are conveyed to the bagging equipment. For those peanuts that are to be salted, they are (b) (4)
(b) (4) The in-shell peanuts are bagged in various sizes.

To be shelled peanuts

Peanuts to be shelled are conveyed (b) (4)
(b) (4) The peanuts are conveyed through a magnet
(b) (4) the peanuts are elevated to the Sheller and (b) (4)
(b) (4)
(b) (4) The peanuts are separated into (b) (4) sizes; (b) (4)
The (b) (4) are used to make peanut butter. From the Sizer, the peanuts are placed into holding bins. The firm has (b) (4) storage bins to pull from. The peanuts are conveyed (b) (4)
(b) (4)
(b) (4)
(b) (4) USDA pulls samples from these bins for grading. Once graded, the peanuts head to the bagging equipment after going through another magnet. They are bagged into (b) (4) totes for peanut butter processing.

Peanut Butter Production Plant

The (b) (4) (totes) of shelled peanuts are transferred to the peanut butter production plant by trucks. A floor diagram of the peanut butter production plant and flow diagram can be viewed in Exhibit #5. The following is the flow (b) (4) (b) (4)
(b) (4)

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(b) (4)

(b) (4)

peanut butter is

passed through a metal detector before going to the filler. (b) (4) See Exhibit #6, photo #44. The peanut butter is filled into jars; the jars are capped; the lids are sealed; the jars are labeled and coded; boxed and palletized for shipment. See Exhibit #6, photos #45 – 52.

(b) (4)

(b) (4) follows basically the same flow diagram. There are several pieces of designated equipment used for the (b) (4)

(b) (4) See Exhibit #6, photos #32, 33, 40, and 41. During the current inspection, the (b) (4) had been inoperable for a week, according to the Grinder Room Operator.

Cleaning/Sanitation Procedures

According to Mr. Pierce, the firm tries to produce product in a water-free environment. Mr. Pierce stated that the firm does not conduct any clean-in-place (CIP). He stated that the equipment is torn down and washed in a sink located in the Grinder Room.

In an effort to determine the firm's cleaning and sanitation procedures, we were provided the following information:

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

Cleaning Room

(b) (4)



Roaster Room

(b) (4)



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After the closeout of the current inspection, I was informed by Mr. Pierce, that during down time the firm would wash the floor in the Roaster Room (b) (4)

(b) (4)

Grinding Room: at (b) (4) the listed tasks should be completed. The responsible operator will sign when each task is completed.

(b) (4)

(b) (4)

Packaging Room: at (b) (4) the listed tasks should be completed. The responsible operator will sign when each task is completed.

(b) (4)

(b) (4)

I requested records showing where the above tasks were being conducted. Ms. Rector provided me copies of records for 10/20/07, the last ones she had on file. I was later faxed, on 11/28/07, copies of records for 10/23/07, the day of the current inspection. See **Exhibit #7** for copies of the records. The records did not reflect the conditions of the rooms the first day of the inspection as depicted in the photos taken of the facility. When we returned the following day to conduct a GMP inspection, the firm had made corrections to the above listed tasks. Therefore, conditions not corrected the following day were placed on a FDA 483 (Inspectional Observations). The ones corrected were discussion items.

Sampling/QC Procedures

(b) (4)

(b) (4) A sample is submitted to (b) (4) for E coli, Salmonellae, coliform, mold, yeast, aerobic plate count and aflatoxin analyses. A sample is maintained for (b) (4) depending on the customer.

Since the current inspection, the firm has implemented an environmental swabbing sampling program where they will periodically test for microorganisms.

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MANUFACTURING CODES

The firm uses a three part coding system for their peanut products that consists of (b) (4)
(b) (4) For example,

L 4045 H 8 C 07

The peanut butter code is a Best by date followed by a (b) (4) For example,

Best by: 24 Oct 08
SU 13:58

COMPLAINTS

There were no complaints listed in FACTS prior to the current inspection. When the firm receives a complaint, they pull the reserve jars of product, investigate the complaint, make a decision, and contact their customer with their decision.

Mr. Pierce stated that the nature of the firm's complaints are pull date not long enough and foreign material (stick).

Ms. Rector provided the firm's Customer Concerns list for 2007 and a page entitled "Things Sunland, Inc. is doing to address Customer Concerns for 2007". On the Customer Concerns list, it lists the types of foreign material found; other complaints such as bad taste, oily, bitter flavor and poor quality; and a sealing problem. The memo entitled "Things Sunland, Inc. is doing to address Customer Concerns for 2007" addresses each column listed on the Customer Concerns list. See **Exhibit #8** for copies of the firm's Customer Concerns For 2007 and "Things Sunland, Inc. is doing to address Customer Concerns for 2007".

RECALL PROCEDURES

The firm does have a written recall procedure. A mock recall is conducted by the firm (b) (4)
The firm had good results with the last two mock recalls. There were no defective products found in the current inspection.

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OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

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

Specifically,

- 1) The employee working in the depalletizer area was observed placing their fingers inside empty jars prior to loading them on the conveyor to the filler where the jars were being filled with ready to eat Organic Creamy Peanut Butter.
- 2) The line supervisor failed to sanitize their hands prior to placing them on the inside the food contact surface of caps for filled jars of Organic Creamy Peanut Butter while placing the caps into the cap hopper.
- 3) The filler operator was observed wiping the filler heads with a plastic spatula, then wiping the removed product on a paper towel and laid the spatula and paper towel on an adjacent table. The spatula was never sanitized and the paper towel was being reused throughout production creating a source for micro contamination.

Annotation:

Reference: 21 CFR 110.80(b)(2)

Supporting Evidence and Relevance:

The employees' practices that were observed during the current inspection constituted an additional source for the firm's finished product to become contaminated with a variety of micro contaminants.

Discussion with Management:

During the walk-through, management addressed each issue prior to leaving the area. At the closeout meeting, management stated that they would respond to the observation in writing.

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In an email dated 10/26/07 forward to me from Sunland, Inc., the firm's response to this observation was as follows:

STATEMENT #1: We are expanding our food safety program TO BE MORE COMPREHENSIVE. THE FOOD SAFETY PROGRAM WILL INCLUDE ADDITIONAL SAFETY PROCEDURES TO FURTHER INSURE PROVIDING OUR CUSTOMERS QUALITY PRODUCTS. ALL EMPLOYEES WILL BE PROVIDED ADDITIONAL TRAINING.

- ❖ #1) Corrective Action: *Employee was retrained on the procedure for handling empty containers entering the filling line. All employees will have additional training for the proper handling of containers. (See statement #1)*
- ❖ #2) Corrective Action: *Line supervisor was instructed not to place hands on the lids when hands were not properly sanitized. (See statement #1)*
- ❖ #3) Corrective Action: *We have started using multiple spatulas during production. The spatulas are stored in empty sanitized containers when not in use and are cleaned, sanitized and dried (b) (4) The paper towels will be used only once and then thrown away. (See statement #1)*

OBSERVATION 2

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

Specifically,

- 1) Grinder^{(b) (4)} was allowed to leak peanut butter onto the floor from the transfer pump seal. The leaking product linked the floor to the pump creating a source for micro contamination to in-process peanut butter.
- 2) The ^{(b) (4)} leaked peanut butter from the pistons and from gaskets on the balance tank creating a source for micro contamination to the finished ready-to-eat peanut butter.
- 3) Process pipes, not in use, were stored uncapped and allowed to make contact with the floor in the grinder room. The floor is subjected to heavy unsanitized foot traffic.

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4) The hand wash sink in the grinder room lacked soap and paper towels.

5) Duct tape was used to repair transfer holes on the hoses on silo^(b)₍₄₎ boot auger and hoses on the air out flow blower on the blanchers.

Annotation:

Reference: 21 CFR 110.80

Supporting Evidence and Relevance:

Discussion with Management:

During the walk-through, management addressed some of the issues prior to leaving the area. At the closeout meeting, management stated that they would respond to the observation in writing.

In an email dated 10/26/07 forward to me from Sunland, Inc., the firm's response to this observation was as follows:

STATEMENT #2: Preventive Maintenance schedule will be reviewed. Focus will be directed at continuous maintenance and immediate repairs as issues arise during production.

- ❖ #1) Corrective Action: ^(b)₍₄₎ by start of production on October 29, 2007. (See statement #2)
- ❖ #2) Corrective Action: ^(b)₍₄₎ by start of production on October 29, 2007. (See statement #2)
- ❖ #3) Corrective Action: Process pipes will be stored where no part of the pipe will make contact with the floor, and the ends will be covered.
- ❖ #4) Corrective Action: Corrected at time of inspection. Hand washing stations will be kept supplied with towels and soap.
- ❖ #5) Corrective Action: Corrected at time of inspection. Employees have been instructed that duct tape is not an acceptable way of repairing equipment. (See statement #1)

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OBSERVATION 3

Employees did not wash and sanitize hands thoroughly in an adequate hand-washing facility before starting work and after each absence from the work station.

Specifically, employees from the grinder and the filler room were observed exiting and entering the process areas without adequate washing and sanitizing their hands before returning to work while manufacturing peanut butter.

Annotation:

Reference: 21 CFR 110.10(b)(3)

Supporting Evidence and Relevance:

Discussion with Management:

At the closeout meeting, management stated that they would respond to the observation in writing.

In an email dated 10/26/07 forward to me from Sunland, Inc., the firm's response to this observation was as follows:

- ❖ *Corrective Action: Our current procedure is for employees to sanitize their hands any time they return to their workstation. We are updating procedures to state that all employees are to wash and sanitize their hands when entering from outside the area.*

OBSERVATION 4

Effective measures are not being taken to protect against the contamination of food on the premises by pests.

Specifically,

- 1) Throughout both warehouses in the peanut and peanut butter facilities, pallets of products are

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being stored too close to the walls of the warehouses creating harborage areas for pest.

2) Your firm has multiple missing and blocked rodent traps in the peanut warehouse and loading dock where shelled and unshelled Valencia peanuts are stored.

3) The firm allows the man door on the load dock to be propped open during production hours.

Annotation:

Reference: 21 CFR 110.35(c)

Supporting Evidence and Relevance:

Discussion with Management:

During the walk-through, management addressed each issue prior to leaving the area. At the closeout meeting, management stated that they would respond to the observation in writing.

In an email dated 10/26/07 forward to me from Sunland, Inc., the firm's response to this observation was as follows:

STATEMENT #3: ALL FORKLIFT EMPLOYEES WILL BE PROVIDED ADDITIONAL TRAINING FOR PROPER USE OF EQUIPMENT. THE ADDITIONAL TRAINING WILL INCLUDE PROPER USE OF EQUIPMENT WITHOUT DAMAGING PRODUCT, AND PLACING PRODUCT IN DESIGNATED AREA CORRECTLY.

- ❖ #1) Corrective Action: *Retraining of employees will be provided for the proper placing of pallets in rows so that they are not extending over the line eighteen inches from the walls. (See statement #1 and #3)*
- ❖ #2) Corrective Action: *Additional training will be provided for employees to make sure rodent traps are in the proper place and that access to traps is not blocked. (See statement #3)*
- ❖ #3) Corrective Action: *Employees have been instructed to keep the door to the loading dock closed.*

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OBSERVATION 5

Failure to store raw materials in a manner that protects against contamination.

Specifically,

- 1) Throughout the peanut processing facility warehouse, your firm was storing multiple damaged bags of shelled and unshelled peanuts while being held for sale.
- 2) Opened boxes of raisins and dried cranberries were stored in the firm's cooler uncovered. According to management, the boxes of raisins and dried cranberries were not to be used in production. The boxes were not identified as to be destroyed or do not use and could have been used to make new products.
- 3) A torn and opened tote of almonds was stored in the firm's cooler. The cooler door has missing drapes that is designed to protect the almonds and other stored raw materials from contamination during processing.
- 4) The firm failed to clean multiple product spillages in both the peanut and peanut butter warehouses. In the peanut butter warehouse the spillages were not limited to chocolate bits spilled over 50lb bags of Certified Organic Sugar and powder egg white spilled on boxes of egg white and bags of wheat germ in the peanut butter production facility which are known allergens.
- 5) Opened bags of starch, sorbitol, sugar, parsley, and garlic powder were stored in the dry storage warehouse in the peanut butter production facility unprotected.

Annotation:

Reference: 21 CFR 110.80(a)(1)

Supporting Evidence and Relevance:

Discussion with Management:

During the walk-through, management addressed each issue prior to leaving the area. At the closeout meeting, management stated that they would respond to the observation in writing.

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In an email dated 10/26/07 forward to me from Sunland, Inc., the firm's response to this observation was as follows:

- ❖ #1) Corrective Action: *Damaged bags will be repaired in a timely manner. Additional training will be provided for forklift operators. (See statement #3)*
- ❖ #2) Corrective Action: *These raw materials were discarded at time of inspection. In the future all raw materials will be properly closed. If special handling is necessary they will be marked with a Quality Control Hold Tag. (See Statement #1)*
- ❖ #3) Corrective Action: *The open bag of almonds was closed at time of inspection. The drapes were replaced at time of inspection. Maintenance has been instructed to be timelier in repairs and forklift operators have been provided additional training in proper use of the forklift. (See Statement #2 and Statement #3)*
- ❖ #4) Corrective Action: *All spillages were corrected at time of inspection. Product will be handled in such a manner that spillages will not occur onto a known allergen. All allergens will be segregated in the storage area with no other items below them in the storage rack. (See Statement #1)*
- ❖ #5) Corrective Action: *All open bags were secured at time of inspection. In the future all material will be secured before being stored. (See Statement #1)*

OBSERVATION 6

Failure to maintain buildings in repair sufficient to prevent food from becoming adulterated.

Specifically, there is a two inch hole in the wall near the air compressor in the peanut warehouse.

Annotation:

Reference: 21 CFR 110.35(a)

Supporting Evidence and Relevance:

Discussion with Management:

At the closeout meeting, management stated that they would respond to the observation in writing.

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In an email dated 10/26/07 forward to me from Sunland, Inc., the firm's response to this observation was as follows:

- ❖ **Corrective Action:** *The two-inch hole in the warehouse is used to service the air compressors. This hole now has a removable cover. The cover was installed 10-25-07.*

A copy of the firm's response email can be viewed in **Exhibit #9**.

REFUSALS

There were no refusals encountered during the current inspection.

GENERAL DISCUSSION WITH MANAGEMENT

On 10/25/07, a closeout meeting was held with Mr. Jimmie D. Shearer, President and CEO; Mr. Paul Newsom, Executive Vice President; Mr. Weston Pierce, Peanut Butter Plant Manager; Ms. Samantha Rector, Quality Control Supervisor; Mr. Mark Bruffett, Production Manager; Analyst Rick A. Crouch, Microbiologist ARL; and me, CSO Charles D. Brown.

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) the initial conditions of the processing equipment at the start of the current inspection; 2) the firm has missing or blocked rodent traps in the Production Plant warehouse; 3) an empty soda bottle was found in the loading dock; 4) products held for destruction not properly identified; 5) the cap sorter in the Peanut Butter Plant is missing a cover; and 6) the firm using duct tape to repair hoses on the silo boot augur and other plastic or rubber hoses throughout the facility. Most of these observations were corrected on-the-spot or prior to our closeout meeting with the firm.

We discussed the buildup of the dust hovering over exposed products during processing. We explained to management that the firm should be aware that, although we were concentrating on salmonella, other microorganisms such as Listeria could be introduced to the finished product during processing, especially in the areas after the in-process product has been cooled. Mr. Pierce earlier stated that he did not feel his plant was in a bad condition. He said he believed that he could produce a quality product. We explained to him that the improvement that we observed on the second day of the inspection lets us know that the initial conditions should not have happened. We explained that

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the firm did not want to wait until there was a problem with their products, but should be doing everything possible to prevent contamination under the GMP regulations.

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 legal sanctions including 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

The firm's pest controller is ^{(b) (4)} [REDACTED] After reviewing some of the pest records, we noted that the pest controller had many notes concerning the conditions in the firm's warehouses. We asked management if the pest controller complained about the warehouse and nothing was done to correct it, how they expected the controller to do an adequate job. We stated that in the firm's defense, we did not observe any rodent pellets in the areas that we could get to.

SAMPLES COLLECTED

One sample (# INV 399193) was collected per the Salmonella Sampling Assignment. A total of 61 subs were collected from the following areas in the Peanut Butter Plant:

Sub #1 was collected from a broom used to sweep the Cleaner Room (vial); *Sub #2* was collected from a push broom used to sweep the Cleaner Room (vial); *Sub #3* is a swab of the floor under the loader in the Cleaner Room (See Attachment #1, Photos #1 and 4); *Sub #4* is a swab of the floor under the picking table in the Cleaner Room (See Attachment #1, Photos #2 and 6); *Sub #5* was collected from a broom used in the Roasting Room (Vial); *Sub #6* is a swab from a drain behind the Blancher in the Roasting Room (See Attachment #1, Photo #11); *Sub #7* is a swab of the floor under the east end (entrance end) of Roaster (See Attachment #1, Photos #7, 8, and 9); *Sub #8* is a swab of the floor under the west end (exit end) of the Roaster (See Attachment #1, Photo #10); *Sub #9* is a swab of the floor under the west exit under the Roaster shaker (North); *Sub #10* is a swab of the floor under the west exit under the Roaster shaker (South) (See Attachment #1, Photo #11); *Sub #11*

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is a swab of the bottom air intake on the north wall from the Roaster (See Attachment #1, Photo #15); **Sub #12** is a swab of the floor on the east end of the Blancher in the Roaster Room (See Attachment #1, Photos #13 and 16); **Sub #13** is a swab of the floor on the west end of the Blancher in the Roaster Room (See Attachment #1, Photos #13 and 16); **Sub #14** is a swab of the slide door of Roaster Storage Tank^{(b)(4)} (See Attachment #1, Photo #17); **Sub #15** is a swab of the floor underneath the slide door of Roaster Storage Tank^{(b)(4)} (See Attachment #1, Photo #18); **Sub #16** is a swab of the entrance way floor into the Grinding Room on the north wall (See Attachment #1, Photo #19); **Sub #17** is a swab of the floor under the Ingredient Feeder on the west end (See Attachment #1, Photos #20 - 23); **Sub #18** is a swab of the floor under the Ingredient Feeder in the middle (See Attachment #1, Photos #20 - 23); **Sub #19** is a swab of the floor under the Ingredient Feeder on the east end (See Attachment #1, Photos #20 - 23); **Sub #20** is a swab of the floor under the in-feed tank in the Grinding Room (See Attachment #1, Photo #24); **Sub #21** is a swab of the drain in the center of the floor of the Grinding Room (See Attachment #1, Photo #29); **Sub #22** is a swab of the floor under Grinder^{(b)(4)} (See Attachment #1, Photo #25); **Sub #23** is a swab of a crack in the floor under Grinder^{(b)(4)} (See Attachment #1, Photos #30 and 34); **Sub #24** is a swab of the floor under the melting tank in the Grinding Room (See Attachment #1, Photo #25); **Sub #25** is a swab of the floor under Grinder^{(b)(4)} (See Attachment #1, Photo #26); **Sub #26** is a swab of condensation around a leaking o-ring on Grinder^{(b)(4)} (See Attachment #1, Photo #26); **Sub #27** is a swab of the floor under Grinder^{(b)(4)} (See Attachment #1, Photo #27); **Sub #28** is a swab of the floor under the aerator in the Grinder Room (See Attachment #1, Photo #28); **Sub #29** is collected from a crack in the floor between the aerator and the ^{(b)(4)} heat exchanger in the Grinding Room (See Attachment #1, Photo #31); **Sub #30** is a swab of the floor under the ^{(b)(4)} heat exchanger in the Grinding Room (See Attachment #1, Photo #31); **Sub #31** is a swab of the floor under the ^{(b)(4)} heat exchanger in the Grinding Room (See Attachment #1, Photo #32); **Sub #32** is a swab of the floor under the ^{(b)(4)} Grinder (See Attachment #1, Photos #40 - 41); **Sub #33** is a swab of the south entrance door in the Grinding Room; **Sub #34** is a swab of the air supply vent near the granulator; **Sub #35** is a swab of the floor under a ^{(b)(4)} conveyor for the ^{(b)(4)} in the Grinding Room (See Attachment #1, Photo #40); **Sub #36** is a swab from Grinder^{(b)(4)} screw auger to pump (See Attachment #1, Photo #30); **Sub #37** collected from discharge from Grinder^{(b)(4)} (See Attachment #1, Photos #26 and 36); **Sub #38** is a swab from conveyor belt on ^{(b)(4)} Feeder (See Attachment #1, Photo #39); **Sub #39** is a swab from the floor under the filler in the Fill Room (See Attachment #1, Photo #43); **Sub #40** is a swab from the top of the control box for the filler (See Attachment #1, Photos #45 and 46); **Sub #41** is a swab from the floor in front of the Filler (See Attachment #1, Photo #44); **Sub #42** is a swab from the floor in front of the capper of the filler (See Attachment #1, Photo #49); **Sub #43** is a swab from the floor in front of the cap hopper of the filler (See Attachment #1, Photo #48); **Sub #44** was collected from a crack in the floor near the ^{(b)(4)} Sealer (See Attachment #1, Photo #50); **Sub #45** is a swab of the floor at the labeling area; **Sub #46** is a swab from the floor at the ^{(b)(4)} Packer; **Sub #47** is a swab of the floor in front of the south entrance of the Fill Room from the Cooler; **Sub #48** is a swab of the floor at the east entrance into the Fill Room; **Sub #49** is a swab of the floor in front of the ^{(b)(4)} Cleaner; **Sub #50** was collected from the screen of the ^{(b)(4)} Cleaner; **Sub #51** is a swab from the slide door of the Roaster Storage Tank^{(b)(4)}; **Sub #52** is a swab from the floor underneath Roaster Storage Tank^{(b)(4)}; **Sub #53** is a swab from the shovel used the floor in the Roasting Room; **Sub #54** is a swab of the boot on the Blancher southwest Discharge Conveyor; **Sub #55** is a swab of the boot on the Blancher middle Discharge Conveyor; **Sub #56** is a

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*swab of the boot on the Blancher southeast Discharge Conveyor; **Sub #57** was collected from the squeegee used to clean the floor in the Roasting Room; **Sub #58** was collected from the mop used to clean the Grinder Room (vial); **Sub #59** was scraping collected from a crack in the floor in the Grinder Room (vial); **Sub #60** was collected from a crack in the floor under the aerator to the heat exchanger in the Grinder Room (vial); and **Sub #61** is a swab from the floor under the equipment wash sink in the Grinder Room.*

Of the 61 subs, one sub, #16, returned positive for Salmonella. The sub was from an entrance door leading into the Grinder Room from the Roaster Room. The entrance door is highlighted on the floor diagram in **Exhibit #5**.

VOLUNTARY CORRECTIONS

The firm voluntarily corrected most of the GMP issues found at the firm. The ones not corrected are awaiting ordered parts.

EXHIBITS COLLECTED

- 1) Copy of the firm's website provide by management (11 pages)
- 2) Product labeling (32 pages)
- 3) Copy of the firm's Organization Chart
- 4) Copy of the firm's Area Diagram
- 5) Copy of the firm's Peanut Butter Plan and flow diagram (2 pages)
- 6) Copies of photos taken of the facility (26 pages)
- 7) Copies of the firm's sanitation logs (17 pages)
- 8) Copies of the firm's Customer Concerns list and Corrective actions sheet (2 pages)
- 9) Copy of the firm's response email (5 pages)
- 10) Copy of the Peanut flow diagram

ATTACHMENTS

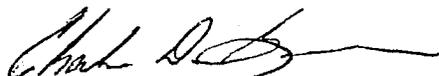
FDA 482 (Notice of Inspection)
FDA 483 (Inspectional Observations)

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Copy of the Salmonella Sampling Assignment (17 pages)


Charles D Brown, Investigator

Ricky A. Crouch, Investigator