

**Establishment Inspection Report**

Sunland, Inc.  
Portales, NM 88130

FEI: 1000117188  
EI Start: 09/21/2010  
EI End: 09/23/2010

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**SUMMARY**

This comprehensive inspection of Sunland, Inc., a peanut/peanut butter manufacturer, was assigned as part of the Denver District FY'10 Performance Goals under FACTS assignment number 1095252. This inspection was conducted in accordance with CP 7303.803, Domestic Food Safety Compliance Program.

The previous inspection was conducted on 3/10/09 by FDA investigators and classified OAI due to a positive environmental sample for Salmonella. The purpose of the inspection was to: follow-up on consumer complaints regarding illness related to Sunland, Inc. products; (b) (4)

(b) (4) and to perform an environmental sample collection. The subsample found positive for Salmonella was not Typhimurium, (b) (4) The firm was notified by phone and promised to re-clean and resample the area where the positive subsample was collected. (b) (4)

(b) (4) The current inspection followed up on the peanuts that were held in quarantine. A "Sunland, Inc. Peanut Roaster Validation" from (b) (4) was provided validating the firm's roaster as a "kill step." The quarantined peanuts were roasted and made into peanut butter.

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The current inspection covered: receiving, storage, shipping, general sanitation, production operations, allergens, recalls and complaints. Records review was conducted on product sample test results, roasting temperature logs, training logs, pest control logs, complaints and production logs.

At the conclusion of the inspection, Mr. Jimmie D. Shearer, President and CEO, was issued a five item 483 citing the following: 1) All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source; 2) Effective measures are not being taken to exclude pests from the processing areas and protect against the contamination of food on the premises by pests; 3) The plant is not constructed in such a manner as to allow floors to be kept in good repair; 4) Failure to wear beard covers in an effective manner; 5) The design and construction of equipment and utensils fails to preclude the adulteration of food with contaminants. Observations not listed on the FDA 483 were discussed with management. The discussion items included raw materials with fork lift damage were observed taped up, restrooms in the peanuts butter production plant lacked hand washing signs, employees entering the production room directly from outside, live bug in the sugar hopper, hair nets too small and no access to certain rodent traps.

FDA Sanctions were provided and discussed and Mr. Shearer who promised to provide a written response letter to the Denver District Director within 15 days.

There were no refusals encountered and no samples taken during this inspection.

Field exams were completed on two products, <sup>(b) (4)</sup> during the course of the inspection. No discrepancies were noted.

A reconciliation exam was performed on a truck load of peanuts. The grading sheet, with the product lot #, from the USDA grading station was not able to be obtained. No discrepancies were observed.

b(3)

b(3)

Food security and the Reportable Food Registry were discussed with Mr. Shearer. A copy of FDA's "Guidance for Industry Food Producers, Processors, and Transporters: Food Security Preventative Measures Guidance" and "ALERT" were provided and discussed.

Post inspectional correspondence, FMD-145, and a copy of the EIR should be addressed to:  
Jimmie D. Shearer, President and CEO  
Sunland, Inc.  
PO Box 1059  
Portales, NM, 88130

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All photos were saved onto a CD-R, placed into an FDA 525, officially sealed, and attached as Exhibit 1.

**ADMINISTRATIVE DATA**

Inspected firm: Sunland, Inc.  
Location: 42593 US Highway 70  
Portales, NM 88130  
Phone: 575-356-6638  
FAX: 575-356-6630  
Mailing address: PO Box 1059  
Portales, NM 88130  
  
Dates of inspection: 09/21/2010-9/23/2010  
Days in the facility: 3  
Participants: Andrea J. Schmidt, Consumer Safety Officer (CSO)  
Carla R. Hinz, CSO

On 9/21/10, we presented our credentials and issued Form FDA 482 to Jimmie D. Shearer, President and CEO of Sunland, Inc. CSO Carla R. Hinz accompanied me, CSO Andrea J. Schmidt, during this inspection. All sections of this report were written jointly by CSOs Schmidt and Hinz.

On 9/23/10, Form FDA 483 was issued and discussed with Jimmie D. Shearer, President and CEO. Form FDA 463a, Affidavit, was signed by Leo Gallegos, Quality Control Manager, documenting interstate movement and allergen procedures.

**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. <sup>(b) (4)</sup>

(b) (4)



Mr. Shearer stated that there are no related companies, including sister companies or subsidiaries.

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The firm currently employs (b) (4) employees; of which (b) (4) are Sunland Inc. full time, and the remaining employees are part time and harvest help. Mr. Shearer stated that the firms' establishment size is between (b) (4)

The firm owns and operates from two main buildings; the Main Plant and the Peanut Butter Plant. The Main Plant is approximately (b) (4) It houses the main offices, retail store and processing for the peanuts. The Peanut Butter Plant is approximately (b) (4) The facility is comprised of the following rooms: peanut cleaning, peanut roasting, grinding, fill, ingredient storage, and finished product and container storage. Since the last inspection the firm has added a finished product supply warehouse (b) (4) and a 2<sup>nd</sup> floor mezzanine (b) (4) (b) (4) to the grinding room of the Peanut Butter Plant. (b) (4)  
(b) (4)

See Exhibit # 8 for Sunland, Inc. Floor Plans

A NM State Department of Agriculture (NMDOA) grading facility exists on the premises.

Mr. Shearer stated that the firm (b) (4)  
(b) (4) The firm makes peanuts into retail ready products such as: peanut butter; peanut butter spreads; roasted and salted peanuts in and out of shell; and raw peanuts in and out of shell. The firm contracts with about (b) (4) peanut growers in (b) (4) and yield a total of (b) (4) (b) (4) of peanuts from a harvest. There are no new products from last inspection; however, new packaging and labeling have been developed.

The previous inspection was conducted on 3/10/09 by FDA investigators and classified OAI due to positive environmental sample for Salmonella. The purpose of the inspection was to: follow-up on consumer complaints regarding illness related to Sunland, Inc. products; (b) (4)

(b) (4) and to perform an environmental sample collection. The one subsample found positive for Salmonella was not Typhimurium. (b) (4)

The firm was notified by phone and they promised to re-clean and resample the area where the positive subsample was collected. (b) (4)

(b) (4)

(b) (4)

A "Sunland, Inc. Peanut Roaster Validation" from (b) (4) was provided validating the firm's roaster as a "kill step." The quarantined peanuts were roasted and made into peanut butter.

See Exhibit # 2 for Sunland, Inc. Peanut Roaster Validation from (b) (4)

b(3)

b(3)

Food security and the Reportable Food Registry were discussed with Mr. Shearer. A copy of FDA's "Guidance for Industry Food Producers, Processors, and Transporters: Food Security Preventative Measures Guidance" and "ALERT" were provided and discussed.

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Jimmie D. Shearer, President and CEO

Sunland, Inc.

PO Box 1059

Portales, NM, 88130

**INTERSTATE COMMERCE**

Mr. Shearer stated the firm sells approximately (b) (4) wholesale and (b) (4) retail. The firm has a retail store as part of their main office. Mr. Shearer stated that (b) (4) of products are shipped interstate throughout the continental US and Hawaii, and internationally to (b) (4). The remaining (b) (4) is sold intrastate (b) (4) is wholesale and (b) (4) retail). Approximately, (b) (4)

The three largest suppliers are:

(b) (4)

Approximately, (b) (4) of finished product is shipped out-of-state. The three largest customers are:

(b) (4)

The firm does not own any delivery trucks. The firm utilizes (b) (4) and third party contractors to deliver products. (b) (4)

(b) (4)

The firm has a marketing department that attends food shows, markets, and visits retail stores. Customers can order product directly from the firm's website at [www.sunlandinc.com](http://www.sunlandinc.com). See Exhibit # 3 for Sunland, Inc. promotional materials

**JURISDICTION**

The firm produces approximately (b) (4) products and utilizes three types of peanuts (runner, Valencia, Spanish). The firm 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. The firm manufactures peanut butter and flavored peanut butter.

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Peanut butters make up (b) (4) of total production, cashew butter and almond butter (b) (4) and (b) (4) Tahini butter (b) (4)

The firm produces and packages finished products utilizing their own brand name as well as products for contract manufacturing customers. Peanut butter products are sent to distribution centers, bakeries and grocery stores. The Sunland brand is distributed to (b) (4) Sunland produces and packages under the following brand names: Sunland (firm's label), Naturally More, Sprouts, (b) (4) Archer Farms, Fresh & Easy, Natural Value, and Josephs.

Raw and roasted in shell and out of shell nuts are sold under the following co-packed labels:  
(b) (4)

See Exhibit # 4 for a product list of processed peanut products. See Exhibit # 5 for a product list of manufactured peanut butter products. See Exhibit # 6 for finished product labels

**INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED**

**Mr. Jimmie D. Shearer, President and CEO** – has been with the firm since 1981. He is the most responsible person; oversees the overall function of the firm, and handles the finances. Mr. Shearer has the overall responsibility to detect, prevent and correct deviations. Mr. Shearer reports to the Chair of the Board of Directors, Garvin Chandler. Mr. Shearer provided us technical and financial information.

**Mr. Paul W. Newsom II, Executive Vice President** – Mr. Newsom has been with the firm for 22 years and in his current position for five years. He is responsible for purchasing (for both peanut and peanut butter plants, manages shipping and production and directly oversees managers and supervisors. Mr. Newsom reports to Mr. Shearer. He answered questions regarding purchasing and operations during this inspection.

**Mr. Leo Gallegos, Quality Control Manager** – Mr. Gallegos has been with the firm since 2008 and has held his current position for 45 days. He is responsible for food safety, product specifications and is responsible bringing the firm to SQF (Safe Quality Food) certification. Mr. Gallegos reports to Mr. Shearer, and he supervises Ms. Rector. Mr. Gallegos accompanied us

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throughout the entire inspection and provided information and records. Mr. Gallegos is still learning all of his duties and the manufacturing processing for his new position.

**Mr. Weston L. Pierce, Peanut Butter Plant Manager** – Mr. Pierce has been with the firm over 10 years and is responsible for the peanut butter plant. He reports to Mr. Newsom, and supervises (b) (6) Gonzales. He has the responsibility to prevent, detect and correct deviations in the Peanut Butter Plant. Mr. Pierce provided us information on the cleaning and sanitizing of the peanut butter plant.

**Mr. Joe Daniel Gonzales, Assistant Plant Manager**-assists Mr. Pierce with the peanut butter production. He reports directly to Mr. Pierce. Mr. Gonzales assisted us in answering questions on the allergens, and cleaning schedules.

**Mr. Mark B. Bruffett, Peanut Production Manager** – Mr. Bruffett oversees the main peanut plant production. He supervises four plant supervisors, oversees shipping and receiving, and schedules production and employees. He has the responsibility to prevent, detect, and correct deviations in the main peanut plant. He reports to Mr. Shearer. Mr. Bruffett provided information on production operations during this inspection.

**Ms. Suzanne M. Zamora, Human Resources Manager** – Ms. Zamora is responsible for all human resources including: hiring, firing, recruiting, and employee training. She reports to Mr. Shearer. She provided us with information on employee training.

(b) (6) **Scheduling** – (b) (6) has been with the firm for 3 years. She is responsible for scheduling, inventory and accounts receivable. She reports to Mr. Newsom. (b) (6) (b) (6) provided us with promotional information and materials.

**Ms. Samantha Rector, Quality Control** – Ms. Rector is responsible for quality control including handling all customer complaints and monitoring results of retain testing. She provided information regarding the complaint process and positive test results of retain samples from Silliker. She reports to Mr. Gallegos. (b) (6) We were able to contact her via telephone to have her explain information on testing results, and consumer complaints.

(b) (6) **Equipment Operator**- is in charge of maintaining peanut plant equipment. He reports to one of the supervisors under Mr. Bruffett. (b) (6) provided us information on the process flow for the peanut plant.

See Exhibit # 7 for an organizational chart.

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**FIRM'S TRAINING PROGRAM**

Upon hire the firm conducts (b) (4) of training/orientation for all employees that include: basic food safety, employee hygiene, and general safety. (b) (4) employee training is conducted and former topics are covered more in depth. The firm utilizes third party contractors such as, (b) (4)  
(b) (4)

**MANUFACTURING/DESIGN OPERATIONS**

**Peanut Plant Process**

**Receiving/grading**

(b) (4)  
(b) (4) Mr. Gallegos explained peanuts must reach moisture content of (b) (4) or below. If the peanuts are below (b) (4) moisture content they are then sent to the NMDOA inspection station to be graded (based on (b) (4) and tested for aflatoxins. Peanuts that measure above (b) (4) moisture content are placed in (b) (4)  
(b) (4) Inedible peanuts are sent for animal feed or oil stock. Peanuts that have tested positive for aflatoxin are sent for oil stock. Mr. Hobbs explained that the oil refining process removes the toxin.

**Processing**

Mr. Hobbs explained that peanuts are placed in (b) (4) barns dependent upon their grade (b) (4)  
(b) (4) peanuts are either shelled or remain in shell.

Note: During our inspection we noticed that the (b) (4) were uncovered and birds were landing in the peanuts. See **Observation 1, #4.**

***Shelled Peanuts*** See Exhibit # 9 for Sunland, Inc. Peanut Flow  
(b) (4)



***In shell Peanuts***

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(b) (4)

***Salted Peanuts***

(b) (4)

**Cleaning of Peanut Process Plant**

Mr. Bruffett stated the cleaning process is constant and on-going. There are (b) (4) people in sanitation dedicated to cleaning that include: sweeping, using pressurized air to blow out areas, and a floor scrubber that uses water and (b) (4) sanitizer. The roaster room is swept continuously with a complete clean (b) (4). The roaster is cleaned out (b) (4) (including: scraping all parts inside and using compressed air to remove residual food debris).

Mr. Bruffett explained that they only clean behind the pallets around the perimeter, walls and ceilings as time permits. CSO Hinz explained that it is important to make time to clean these areas as time may not be available during the busy season. During the inspection we discussed the amount of peanut dust and particle build up that we noticed on the walls and ceiling with Mr. Gallegos and Mr. Bruffett. Both gentlemen agreed the walls and ceilings needed more attention to cleaning.

**Peanut Butter Plant (Process)**

**Employee Hygienic Practices**

Prior to entering the Peanut Butter Plant processing area, all employees don a hairnet and beard cover (as appropriate), enter the production room, don a new smock, wash/rinse/dry/sanitize hands, and don disposable gloves. Mr. Gallegos stated that employees are to wear a new smock every day and change it out as they become soiled. He explained that smocks are laundered off site by (b) (4) (a contracted laundry company).

**Sanitation**

The firm conducts (b) (4) testing after sanitizing to ensure proper cleaning. If the (b) (4) is positive the procedure is to re-clean and re-test. The (b) (4) swabbing records were reviewed and (b) (4) count ranged from (b) (4) and results (b) (4) were re-cleaned and re-tested. The floors are swept (b) (4) and walls and ceilings are cleaned (b) (4).

Note: Mr. Pierce stated that only some of the equipment that is cleaned after positive (b) (4) swabbing, is retested with the (b) (4) swab.

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Mr. Gallegos explained they do not currently maintain sanitation logs. The firm has a separate cleaning room located adjacent to the grinding room for cleaning out of place equipment. The firm uses (b) (4) sanitizer and (b) (4) soap for cleaning. We noticed that the floor in this room was in disrepair with exposed aggregate (see **Observation 3, #1**).

Mr. Gallegos explained that they use a (b) (4) system for their buckets in this room to prevent cross contamination. He explained that (b) (4)

**Cleaning Room**

Raw, shelled peanuts are received in totes weighing up to (b) (4) from the Main Plant, or from other suppliers via trucks, to the receiving room. If peanuts come from another supplier, they come with an aflatoxin report and lot numbers (b) (4). Lot numbers are on tags placed on the totes. These lot numbers are traced throughout production on the production sheets. The peanuts are fork lifted to the cleaning room where they go through a cleaning process as follows: (b) (4)

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

**Cleaning of Cleaning Room**

Floors are swept (b) (4)

**Roasting Room**

(b) (4)

(b) (4)

(b) (4) Mr. Gallegos stated that the roaster can roast up to (b) (4) pounds per hour. He stated that the magnets are checked (b) (4) and they have found things such as metal shavings and screws on them.

**Cleaning of Roaster and Roasting Room**

The roaster is cleaned (b) (4) and blowing off residual debris with compressed air. The floor is swept (b) (4) Mr. Gallegos (b) (4)

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**Grinding Room**

The (b) (4) Line (b) (4)

The (b) (4) line is used to make the following peanut butters: (b) (4)  
(b) (4) and (b) (4) See Exhibit #10 for Sunland, Inc. Peanut butter Flow  
(b) (4) line.

(b) (4)

(b) (4) Mr. Gonzales stated that the line is capable of running up to (b) (4) pounds of peanuts/hour. Mr. Gallegos stated that metal detectors are checked (b) (4) and product is automatically diverted into a dump bin if metal is detected. He stated that they used (b) (4) to check the metal detectors.

Note: Temperatures are caused by the grinding process; there is no significance other than they need to be cooled back down. Mr. Gallegos explained that (b) (4) is used in the chillers to bring temperature down. He explained that the chillers are (b) (4)  
(b) (4) Mr. Gallegos stated that they have (b) (4)  
(b) (4)

**The (b) (4) Line**

The (b) (4) line is used to make (b) (4) peanut butters (b) (4)  
(b) (4) (b) (4)  
(b) (4) Mr. Gallegos stated that (b) (4) is tempered at (b) (4) See Exhibit # 11 for Sunland Inc.  
Peanut Butter Flow (b) (4)

(b) (4)

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(b) (4) Line

(b) (4)

Note: During our inspection we observed the bar with the brush, used to make an even flow of peanuts on the (b) (4) line, was rusted and not easily cleanable. See **Observation 5, #1**.

*Mezzanine on 2<sup>nd</sup> Floor* (New area since the previous inspection, located in Grinding Room)

(b) (4)

(b) (4) Line (located in Grinding Room)

(b) (4)

Cleaning of (b) (4) Line

Mr. Gallegos stated that the equipment used in the (b) (4) process can be completely broken down, washed/rinsed/sanitized in the three compartment sink, and air dried.

**Cleaning of Grinders and the Grinding Room**

Grinders on the (b) (4) line are cleaned in place (b) (4) Mr. Gallegos stated that grinders (b) (4) are broken apart, scraped (b) (4) brushed (b) (4) (b) (4) rinsed (b) (4) and sanitized (b) (4) (b) (4)

Cleaning of (b) (4) Line

Mr. Pierce stated the (b) (4) line does not come apart to allow for cleaning and sanitizing. (b) (4) hoppers are only given a dry wipe between ingredients, See **Observation 1, #1**. The line itself never is broken down. Mr. Pierce explained that a (b) (4) is performed after products that have either wheat germ or egg whites as an ingredient. (b) (4)

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(b) (4) Mr. Pierce explained that once a year they perform an allergen test on product that comes out at (b) (4) See **Evidence and Relevance** section of **Observation 1, #1**.

**Cleaning of (b) (4) Line**

Mr. Pierce stated the (b) (4) line is broken down, cleaned, sanitized, and air dried using (b) (4) Sanitizer levels were checked at the time of inspection and tested at (b) ppm. After cleaning and sanitizing the equipment is (b) (4) swabbed and tested before put back into use. Mr. Gallegos explained that the (b) (4) line (b) (4) are only cleaned if a new product is going through. He stated that otherwise the old product residual remains in the equipment.

**Fill Room**

Mr. Pierce stated that there are (b) (4) fill lines in this room (b) (4) He stated that they can run (b) (4) Lines observed in operation include (b) (4) (b) (4) (b) (4) (b) (4)

(b) (4) Line-used to fill products (b) (4) (b) (4)

(b) (4)

Mr. Gallegos explained that QA checks for the right label (on jar), right date, and right label on every box.

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(b) (4) *Line Filler*-used to fill (b) (4)  
(b) (4) All filling happens behind (b) (4)

(b) (4)

(b) (4) The old line can run (b) (4) batches.

A QA technician checks (b) (4) for weight and retain samples.

(b) (4)

(b) (4) used to fill (b) (4) This line was not observed in operation during the inspection. (b) (4)

(b) (4)

(b) (4) used to fill (b) (4) This line was not observed in operation during the inspection.

Note: Mr. Gallegos explained that all peanut butter products are stored in a walk-in (b) (4) refrigerator for (b) (4). He explained that they try to keep the room at (b) (4). The room measured (b) (4) during the inspection; however, the door was open as product was being staged inside.

**Cleaning of Fill Lines** (from grinding room to end of fill head)

Mr. Pierce stated that the both fill lines can not be broken down and do not get cleaned and sanitized.

(b) (4)

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**Cleaning of (b) (4) Line Filler**

Mr. Gallegos stated that this line is cleaned as needed. He explained if no product will be run for a week or more they will clean the filler. He explained that this filler is usually used only about every (b) (4). Cleaning consists of removing hopper, fill heads, and tray molds, and taking them to the cleaning room to be washed/rinsed/sanitized in the three compartment sink, and air dried. Mr. Gallegos explained that the QA technician performs (b) (4) swabbing and testing to ensure equipment is cleaned. He stated that gaskets are checked and changed as needed and if reusable they are washed/rinsed/sanitized with the other removable pieces. Pieces that can not be removed (non-food contact sections) are cleaned in place.

The firm receives their water supply from the (b) (4). Mr. Gallegos stated that they monitor the annual test results from the city and send in one sample for testing (b) (4). The firm contracts with (b) (4) for waste disposal once to twice a week or as needed.

**Cleaning Fill Room**

Mr. Pierce stated that the floors, walls and ceilings are cleaned about once a month. He stated that floors are swept as needed and mopped with (b) (4) to remove nut oils, and walls and ceilings are cleaned with (b) (4).

**Warehouse Storage (Peanut Butter Plant)**

The firm has a new (b) (4) storage warehouse used to store finished product, packaging materials and a quarantine area for finished products. Mr. Gallegos stated that the quarantine area has been segregated for products that either do not meet quality standards, or are otherwise awaiting a final disposition. He stated that the warehouse floor is cleaned (b) (4). He explained that different parts are cleaned every day, not the whole warehouse floor every day.

Note: Mr. Pierce stated that flies are a constant issue in the production plant (roasting room, grinding room, and fill room). According to Mr. Pierce, traps are changed (b) (4) and bait is placed outside. Flies were observed through out the plant see **Observation 2, #2**.

**QUALITY CONTROL**

Mr. Pierce explained that the firm conducts environmental swabbing (b) (4) locations including drains and other random areas. The firm uses (b) (4). (b) (4) He explained that if they have a positive, they clean/sanitize (per their SOP) and re-swab. Mr. Pierce stated that they always test drains and the areas that have been positive in the past. He explained that the remaining swabs are at random. The swabs are sent to (b) (4) for test analyzing. Ms. Gallegos stated that there have been two positives since the last FDA inspection; however, the re-testing came back negative.

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The firm tests retain samples of finished products. (b) (4)  
(b) (4) Mr. Gallegos stated that they ship (b) (4) to test for Salmonella, E. Coli, Coliform, alfatoxin, APC, yeast, and mold. (b) (6) stated that the firm holds all finished products until the test results from (b) (4) are reviewed. She stated that if the firm receives a positive test result, the lot is tested again. If the second test passes, product is released. If the second test does not pass, the product is disposed (b) (4) and the firm documents the product destruction. (b) (6) stated the firm has had positives for salmonella in the finished product, with the last instance (b) (4) She stated that product was (b) (4)

Mr. Shearer stated that the firm reworks some product, mostly due to label issues. Occasionally (b) (4) the product is reworked out of the jar due to the wrong consistency of the product (fine vs. coarse). (b) (4)  
(b) (4) Since the grinder is after the roasting process, there is no kill step during this process.

**ALLERGENS**

The firm manufactures one product, (b) (4) on the (b) (4) production line that contains wheat germ and egg whites. Mr. Gonzales stated this production line is unable to be broken down, cleaned and sanitized to remove allergen residue. The egg whites are added at the ingredient hopper in (b) (4)  
(b) (4) The hopper only receives a dry wipe between ingredients. The firm conducts a (b) (4) to remove allergen residue. See **Evidence and Relevance for Observation 1, #1**, of this report for more detailed information.

There are no criteria for allergen monitoring. Most products are labeled with a cautionary allergen statement claiming products are manufactured in a plant that uses allergens in production (See Observation 1, #1). See Exhibit # 12 for Allergen Test Results.

**MANUFACTURING CODES**

The firm uses a BEST BY date on all finished product jars and a date (b) (4)  
(b) (4) An example is as follows:  
BEST BY: 21SEP11  
08:26

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**COMPLAINTS**

Ms. Samantha Rector, Quality Control, is responsible for handling customer complaints. Ms. Rector stated that customers call her with their complaint and she informs the customer to return the product. The firm investigates the complaint and follows-up with the customer. If the complaint pertains to illness, the firm performs an investigation and reviews the records of the sampled lots. The firm sends the returned product and the retain sample, from the same lot, to (b) (4) for testing. Mr. Pierce stated that can get retain samples that are within (b) (4) of production of the customer's returned product. Mr. Rector stated that if the complaint pertains to injury the firm sends the product to their insurance company for them to handle it. Ms. Rector stated they have not had any positive results (for Salmonella, and E. coli) on customer returned products. All complaints are maintained in the firm's complaint log. We reviewed the complaint log over a 4 month period and observed the majority of complaints were regarding quality, five complaints pertained to foreign materials in products, and one regarding illness. The last complaint regarding illness occurred the week before the inspection and results were pending from the lab.

**RECALL PROCEDURES**

Incoming peanuts from the farm that pass grade are issued lot numbers by the NMDOA grading station and then are tracked throughout manufacturing. The firm manufactures (b) (4)  
(b) (4)

The firm has a written Crisis Management Recall Program. Mr. Shearer stated they can not track back to the grower because the peanuts are comingled; however, the firm can trace back from the point at which the peanuts are graded by the NMDOG and given a lot number, and trace forward to individual jars based on the BEST BY date. The firm generates a production log that lists all ingredients by lot number that corresponds with the finished product jar code.

Mr. Gallegos stated that they conduct mock recalls and the firm's customers perform mock recalls on them. He stated that the firm has not had an actual recall.

**FIELD EXAMS**

Field exams were completed on the following products and no discrepancies were observed:

(b) (4)  
[Redacted area]

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**RECONCILIATION EXAM**

A reconciliation exam was performed on a truck load of peanuts. The grading sheet, with the product lot #, from the USDA grading station was not able to be obtained. No discrepancies were observed.

**ADDITIONAL INFORMATION****Pest Management**

The firm contracts with (b) (4) for pest management. Mr. Gallegos stated that (b) (4) come (b) (4) to monitor bait traps outside and (b) (4) traps inside. See **Discussion Item 6.**

**Corrections from Previous Inspection****Observations**

1. The (b) (4) was repaired and no longer leaking.
2. The (b) (4) on the (b) (4) line was cleaned and did not have old food residue build up on it.
3. The gaskets on the lids of the ingredient hoppers were removed so that they do not flake off into product.

**Discussion Items**

1. The insulation above grinder (b) (4) was repaired and intact.

**Animal Feed**

Mr. Newsome explained that all scrapings (skins, shells, bad/small peanuts) are sold for cow feed to local farmers.

**Sick Employee Policy**

Mr. Gallegos stated that they encourage their employees not to come in if they are sick. He stated that supervisors are instructed to send employees home if they display signs of a cold, are coughing, or sneezing. CSO Hinz asked if they monitor for frequent trips to the restroom that could indicate diarrhea and possible foodborne illness. Mr. Gallegos stated that they have not considered monitoring for this. CSO Hinz encouraged them to do so.

**OBJECTABLE CONDITIONS AND MANAGEMENT'S RESPONSE**

On 9/23/10, a close-out discussion was held with Jimmie D. Shearer, President, Paul W. Newsom, Vice President, Weston L. Pierce, Peanut Butter Plant Manager, Mark B. Bruffett, Peanut Production Manager, Leo Gallegos, Quality Control Manager, and CSOs Schmidt and Hinz. A five item FDA-483 was issued to Jimmie D. Shearer, President. FDA Sanctions were provided and discussed. Mr. Shearer promised a written response to Denver District's Director within 15 days.

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**Observations listed on form FDA 483**

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**OBSERVATION 1**

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

Specifically,

- 1.) On 9/21/10, a mixture of dried egg whites and sugar was observed in the sugar hopper on a shared line for products without egg whites. It was explained that only dry wiping is performed on the hopper in between ingredients and no cleaning is performed on the main lines.
- 2.) On 9/22/10, an employee that was monitoring lid integrity was observed touching the food contact side of the lid when applying it to the finished product containers. The employee was then observed performing another task involving touching non food contact surfaces and then returning to applying lids and touching the food contact surface of the lid. The employee did not wash hands or change gloves between the two tasks.
- 3.) On 9/22/10, an employee working the de-palletizer was observed utilizing a metal t-shaped tool to upright fallen jars. The metal tool was observed touching the inside of finished product containers.
- 4.) On 9/21/10 and 9/22/10, peanuts were observed outside in trailers uncovered and open to the elements. Birds were observed in and flying over the peanuts.

Reference: 21 CFR 110.80

Supporting Evidence and Relevance

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Photo 021, 9/21/10, AJS, shows egg white residue on the side of the hopper with sugar in it.

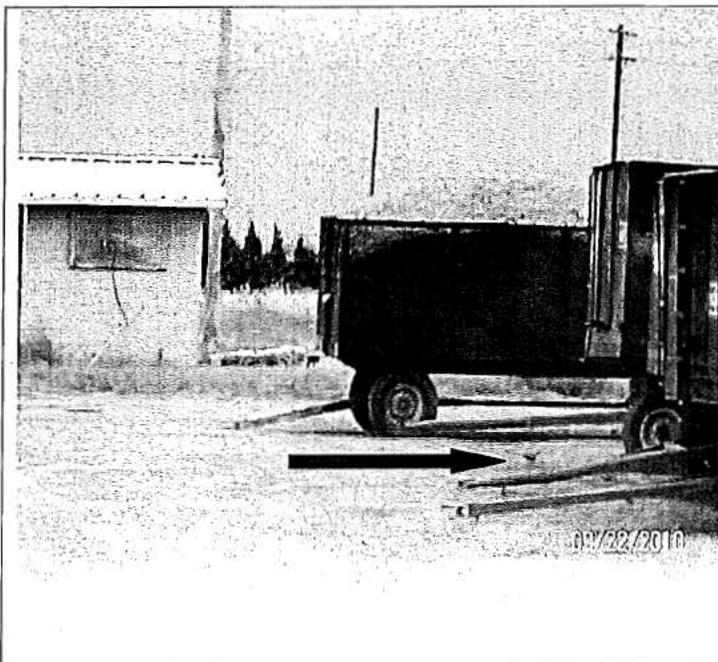


Photo 057, 9/22/10, AJS, shows peanuts outside in trailers uncovered and open to the elements and birds on the ground eating peanuts.

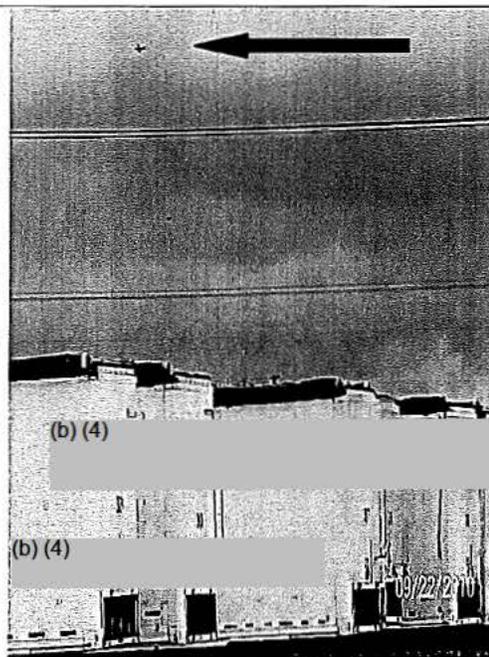


Photo 058, 9/22/10, AJS, shows peanuts outside in trailers uncovered with a bird flying over.

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1.) Egg whites and wheat germ are used in the manufacturing of (b) (4) (peanut butter blend), which is made on the (b) (4) line that is also used for various other peanut butter products. Mr. Pierce stated this production line is not cleaned and sanitized to remove allergens between the production of the (b) (4) peanut butter blend and other peanut butter products. He stated that they perform (b) (4) of peanut butter, to reduce the allergen concentration. Mr. Pierce explained that (b) (4) they take a sample and send it in for testing for wheat germ and egg whites, the two allergens used in these products. Mr. Pierce explained that their testing threshold is (b) (4). He stated that this means as long as their tests came back with a trace of wheat germ and egg whites both reading at (b) (4) or less, that the (b) (4) was adequate. The tests results showed 25ppm for both products in Exhibit #12.

2.) Employees touching non-food contact surfaces then food contact surfaces without washing their hands in between tasks can cause cross contamination to occur into the finished product.

3.) Tools used to upright fallen jars, that touch the inside (food contact-portion) of the jar, shall be stored and used in a manner that will prevent them from contaminating the food contact surfaces. The t-shaped tool was previous observed stored on top of the equipment used to control the conveyor. This was not a sanitary method to store this tool. This tool also was not frequently washed, rinsed or sanitized. The only cleaning of the jars down the line, prior to fill, includes a suction of air to remove any debris.

4.) Birds were seen in and flying around uncovered peanuts. Uncovered peanuts can be an attractant to birds and insects which could lead to possible contamination/adulteration of the product.

**Discussion with Management.**

1.) We explained our concern regarding cross-contamination of allergens and according to CPG Sec. 555.250, Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens, "a firm must identify and implement controls to prevent potential allergen cross-contact, e.g. dedicated equipment, separation, production scheduling, sanitation, proper rework usage (like into like)." Mr. Gallegos agreed that they needed to develop a better way to remove the allergens; he stated that this was something that they were considering for their (b) (4)

2.) Mr. Pierce stated the firm would retrain the employees and (b) (4) (b) (4) so that they would not have go back and forth between food contact and not food contact surfaces.

3.) After we brought this to the attention of Mr. Gallegos (on 9/22/10), and he observed what employees were doing, he agreed to come up with a better method to handle the fallen jars.

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4.) Mr. Jimmie Shearer stated that he considered the peanuts still the farmer's product and as such considered them a raw agricultural product. Per Mr. Shearer, the peanuts are not his product until they pass grade and are placed in the barn.

We explained to Mr. Shearer, that once the peanuts are on his property, they are his responsibility to ensure that further contamination does not occur. These peanuts are in the process of being dried, which is a processing step. We explained that it did not matter who owned the peanuts.

**OBSERVATION 2**

Effective measures are not being taken to exclude pests from the processing areas and protect against the contamination of food on the premises by pests.

Specifically,

1.) On 9/21/10 the East and West rolling dock doors, and roaster room rolling dock door in the main plant was observed open without adequate screening. Flies were observed in the main plant during production.

2.) On 9/22/10, the cleaning room dock door was observed open without adequate screening and the adjoining door to the roaster room in the production plant was observed open. Flies were observed in the roasting room, grinding room, and fill room of the production plant during production. Flies traps were observed completely full.

Reference: 21 CFR 110.35 (c)

**Supporting Evidence and Relevance**

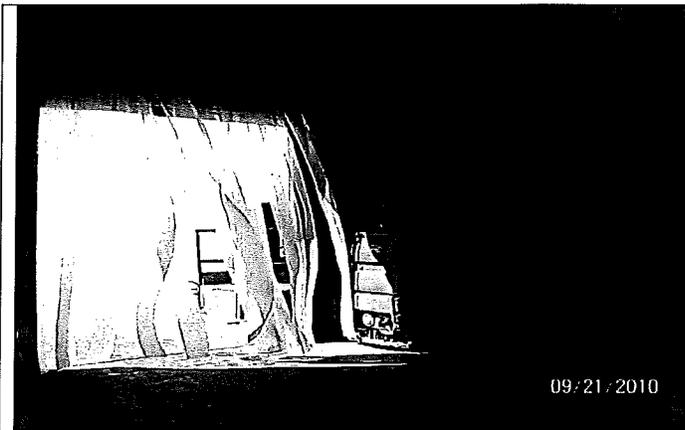


Photo 010, 9/21/10, AJS, shows the east dock rolling door of the Main Plant open without proper screening and finished product in mesh bags next to the door.

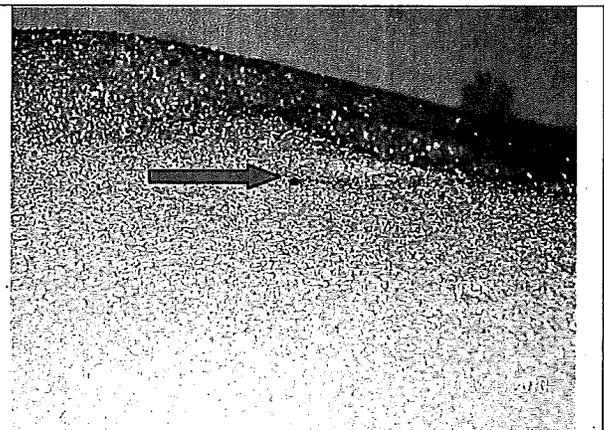


Photo 021, 9/21/10, AJS, shows a live insect in the sugar ingredient feed in the Peanut Butter Plant.

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(b) (4)

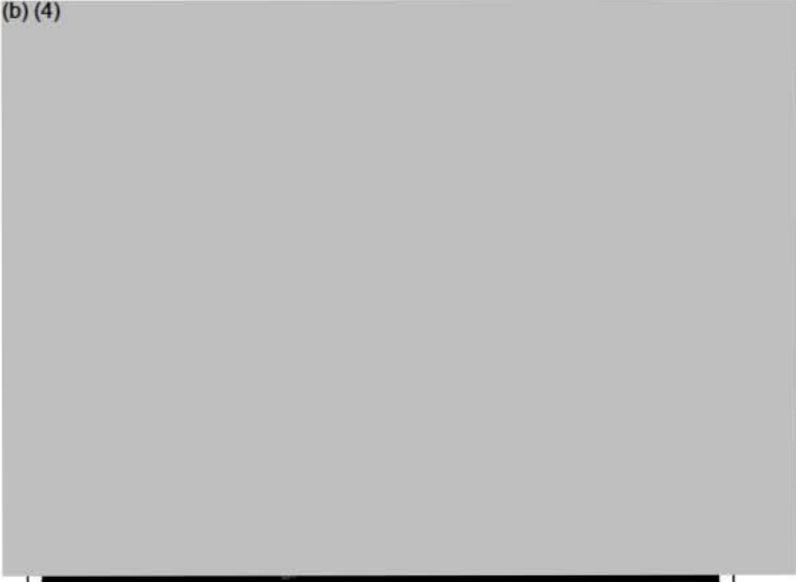


Photo 053, 9/22/10, AJS, shows the fly traps completely full of bugs in the Peanut Butter Plant.

1- 2) Open doors without adequate screening allow pests and debris to enter from the outside into the facility. Both production plants had dead insects along the inside perimeter of the facility and live flies throughout the facility. Flies were seen on product during the manufacturing process and could be a source of contamination. A live insect was also found in the sugar ingredient feed and fly traps were observed completely full of bugs.

**Discussion with Management**

1-2) Mr. Bruffett explained that the dock doors of the main plant are left open (b) (4) for ventilation. He stated that they could insert plastic curtains or air screens in front of all of the doors. We explained that screens are methods to control flies while the doors are open to move product in and out, but should not be considered a permanent exclusion method for the rest of the time. Mr. Bruffett agreed to research alternate methods of providing ventilation so that the doors can remain closed. He agreed to have his time frame of correction included in the 15 day response letter.

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**OBSERVATION 3**

The plant is not constructed in such a manner as to allow floors to be kept in good repair.

Specifically,

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1.) On 9/21/10, exposed aggregate and cracks were observed on the washroom floor in the production plant.

Reference: 21 CFR 110.20 (b)(4)

**Supporting Evidence and Relevance**



Photo # 031, 9/21/10, AJS, shows exposed aggregate on the washroom room of the Peanut Butter Plant



Photo # 032, 9/21/10, AJS, shows exposed aggregate and cracks on the washroom floor of the Peanut Butter Plant

1.) Exposed aggregate and cracks in the washroom floor are harborage areas for microorganisms and make it difficult to clean adequately making it a possible source of contamination.

**Discussion with Management:**

1.) Mr. Pierce agreed to the observation and stated that the floors would be corrected with in 60 days.

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**OBSERVATION 4**

Failure to wear beard covers in an effective manner.

Specifically,

- 1.) On 9/22/10 an employees was observed not covering his mustache with the beard cover.

Reference: CRF 110.10 (b)(6)

**Supporting Evidence and Relevance**

- 1.) This is a repeat violation from the previous inspection. Failure to wear a beard cover properly can lead to facial hair in the finished product.

**Discussion with Management**

- 1.) On 9/23/10, during closeout discussion, no comment was made by management. On 9/22/10 when we brought this concern up to Mr. Gallegos in the peanut butter fill room, he stated that USDA did not require that mustaches be covered. We explained to him that they also fall under FDA regulations and under the current Good Manufacturing Practices, all hair shall be restrained.
- 

**OBSERVATION 5**

The design and construction of equipment and utensils fails to preclude the adulteration of food with contaminants.

Specifically,

- 1.) On 9/21/10 the device used to spread the peanuts out on the crunchy machine was observed rusty.

Reference: 21 CFR 110.40 (a)

Supporting Evidence and Relevance:

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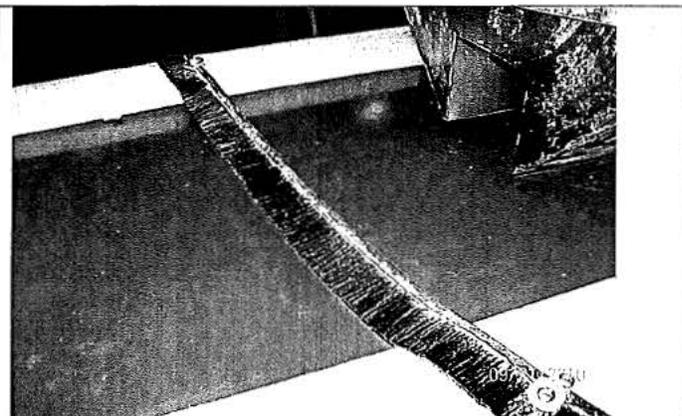


Photo # 028, 9/21/10, AJS, Photo of the rusty bar, on the (b) (4) picking line, that spreads the peanuts out for the pickers to pick out debris, such as twigs and rocks.

1.) The (b) (4) line (machine) is a piece of equipment that spreads out the peanuts enabling the pickers to pick out debris, such as sticks and rocks. The peanuts sent through this piece of equipment are used in the (b) (4) peanut butter and are not subject to a kill step before entering the finished product. A rusty piece of equipment that is in contact with the finished product could be a source of contamination because it is difficult to clean properly and is a harborage area for microorganisms.

### Discussion with Management:

1.) Mr. Weston Pierce stated he would replace the rusty part with stainless steel by the end of the month.

### REFUSALS

No refusals were encountered during this inspection.

### GENERAL DISCUSSION WITH MANAGEMENT

On 9/23/10, a close-out discussion was held with Jimmie D. Shearer, President, Paul W. Newsom, Vice President, Weston L. Pierce, Peanut Butter Manager, Mark B. Bruffett, Peanut Production Manager, Leo Gallegos, Quality Control Manager, and CSOs Schmidt and Hinz. A five item FDA-483 was issued to Jimmie D. Shearer, President. Mr. Shearer promised a written response to Denver District's director within 15 days.

The following items were not included on the FDA-483 but were discussed with management:

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**Discussion Item 1**

On 9/21/10, a bag of raw material (b) (4) in the warehouse was observed to have fork lift damage. The bag was punctured open in two places and was taped up to hold the raw materials in. This was brought to the attention of Mr. Gallegos on 9/21/10. I explained to Mr. Gallegos that the damaged raw materials could be contaminated by the fork lift and questioned what the firm's policy was regarding damaged goods. Mr. Gallegos stated the firm's policy is to discard damaged goods. The damaged raw materials were disposed of during the inspection.

**Discussion Item 2**

On 9/22/10, we observed that the employee restrooms of the peanut butter production plant lacked hand washing signs reminding them to wash their hands after using the restroom. Mr. Gallegos was notified of the observation and stated he would post a hand washing sign immediately.

**Discussion Item 3**

During the course of the inspection, we observed employees entering the peanut butter production plant after walking across the dirt parking lot/road. We notified Mr. Pierce of our observation and concern with bringing contamination from outside directly into the production area. Mr. Pierce stated they have tried a series of methods to minimize the amount of contamination such as booties, but they were not durable enough. (b) (4)  
(b) (4)

**Discussion Item 4**

On 9/21/10, we observed a live insect crawling on top of the sugar in the sugar ingredient feeder. Mr. Gallegos witnessed the insect and agreed that an insect in raw materials is not acceptable. Mr. Gallegos discarded the sugar during the inspection. During the close-out discussion, Mr. Gallegos stated they would monitor more closely for pests. Mr. Gonzales stated that he has never seen any lives insects in the ingredients before.

**Discussion Item 5**

During the course of the inspection, we observed the employees' hairnets were not adequate size to fully cover and contain the employees' hair. We explained that inadequate hairnets defeat the purpose of a hair restraint. Mr. Gallegos agreed and stated he would order larger hair nets.

**Discussion Item 6**

On 9/23/10, the pest control logs were reviewed and we observed on numerous occasions there was no access to various rodent traps. We explained if the pest control servicemen can not access the traps, they are unable to assess the amount of rodent activity in that area. During the close-out discussion management agreed that is was an issue, no further comments were made.

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**SAMPLES COLLECTED**

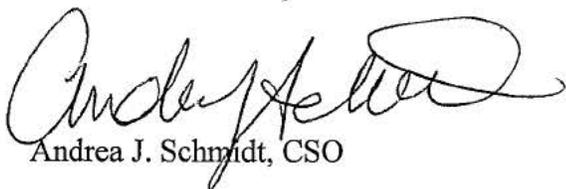
No samples were collected during this inspection.

**EXHIBITS COLLECTED**

- Exhibit 1 FDA 525 containing disc of original digital photographs taken during inspection
- Exhibit 2 Sunland Inc. Peanut Roaster Validation, 6 pages
- Exhibit 3 Sunland Inc. Promotional Materials, 4 pages
- Exhibit 4 Product list of processed peanut products, 1 page
- Exhibit 5 Product list of manufactured peanut butter products, 8 pages
- Exhibit 6 Finished Product Labels, 3 pages
- Exhibit 7 Organizational Chart, 1 page
- Exhibit 8 Sunland Inc. Floor Plans, 3 pages
- Exhibit 9 Sunland Inc. Peanut Flow, 1 page
- Exhibit 10 Sunland Inc. Peanut Butter Flow (b) (4) Line, 1 page
- Exhibit 11 Sunland Inc. Peanut Butter Flow (b) (4) Line, 1 page
- Exhibit 12 Allergen Test Results

**ATTACHMENTS**

- FDA 482, Notice of Inspection dated 9/21/2010, 1 page
- FDA 483, Inspectional Observations dated 9/23/2010, 2 pages

  
Andrea J. Schmidt, CSO

  
Carla R. Hinz, CSO