

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

6th & Kipling St. (P.O. Box 25087)
Denver, CO 80225-0087
(303) 236-3000 Fax: (303) 236-3100
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

09/17/2012 - 10/16/2012*

FEI NUMBER

1000117188

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jimmie D. Shearer, President

FIRM NAME

Sunland, Inc.

STREET ADDRESS

42593 US Highway 70

CITY, STATE, ZIP CODE, COUNTRY

Portales, NM 88130

TYPE ESTABLISHMENT INSPECTED

Peanut Butter Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

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

Specifically,

- A. Since 2009, your firm has distributed lots of peanut butter and nut butters that were positive for Salmonella. The following is a list of products since 2009 that have been manufactured by your firm, have tested positive for Salmonella by your firm's internal testing program, and were at least partially distributed by your firm.

Date	Product ID	Product Type	Salmonella Type
6/10/2009	040048	Peanut Butter	S. Newport
6/10/2009	000436	Peanut Butter	S. Newport
6/10/2009	000437	Peanut Butter	S. Newport
6/10/2009	000439	Peanut Butter	S. Newport
6/10/2009	000438	Peanut Butter	S. Newport
8/30/2009	026909	Peanut Butter	S. Othmarschen, or S. Oranienburg, or S. Winston, or S. Oakey
3/20/2010	081955	Peanut Butter	S. Dallgow
3/20/2010	003385	Peanut Butter	S. Dallgow
2/2/2011	030917	Peanut Butter	S. Dallgow

AMENDMENT 1

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EMPLOYEE(S) SIGNATURE

Jamie L. C. Dion, Investigator *Jamie L. C. Dion*
Brent W. Higgs, Investigator
Daniel J. Lahar, Investigator
Isabel Y. Espinosa, Investigator *Isabel Y. Espinosa*
Gloria A. Milster, Investigator
Edith M. Gonzalez, Investigator

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8/18/2011	000004	Peanut Butter	S. Arapahoe
8/19/2011	000050	Peanut Butter	S. Teddington
8/19/2011	000051	Peanut Butter	S. Teddington
8/19/2011	000050	Peanut Butter	S. Cerro
9/19/2011	071119	Peanut Butter	S. Mbandaka
9/23/2011	000432	Peanut Butter	S. Mbandaka
9/23/2011	071119	Peanut Butter	S. Mbandaka S. Kubacha
6/19/2012	011201	Peanut Butter	S. Bredeney
7/14/2012	026704	Peanut Butter	S. Bredeney
8/23/2012*	002334	Almond Butter	S. Meleagridis
8/23/2012	900251	Almond Butter	S. Meleagridis
8/23/2012	900250	Almond Butter	S. Meleagridis

(* This lot of Almond Butter was part of a composite that tested positive for S. Meleagridis by your firm and was released by Quality Control for distribution. At the time of the Observation this lot had not been distributed.)

B. During the current inspection, the following samples of finished products were collected from your firm by FDA and tested positive for Salmonella. The products listed below were not identified as being positive for Salmonella by your firm.

Date of Manufacturing	Product Sample #	Product ID	Product Type	Salmonella Type
05/22/2012	501133	071119	Peanut Butter	S. Bredeney
05/23/2012	501134	071119	Peanut Butter	S. Bredeney
06/20/2012	501140	000007	Peanut Butter	In-progress
06/20/2012	501143	011202	Peanut Butter	In-progress
09/20/2012	501148	013210	Shelled Raw Valencia Peanuts	In-progress

C. During the current inspection, the following environmental samples were collected from your firm by FDA and tested positive for Salmonella:

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TYPE ESTABLISHMENT INSPECTED

Peanut Butter Manufacturer

Sample/Sub#	Location –Peanut Butter Plant	Salmonella Type
INV722153/1	Peanut Butter Plant: Roasting Room, NW corner of the air duct located on the north side of Roasting Room.	In-progress
INV722153/3	Peanut Butter Plant, Roasting Room, Cement floor crevice just off the E corner of 2nd North wall j-box from NE corner.	In-progress
INV722153/4	Peanut Butter Plant: Roasting Room, Area just below hopper base of in-feed elevator E. corner.	In-progress
INV722153/5	Peanut Butter Plant: Roasting Room, Gouge in cement crack just W. of the in-feed elevator leg and E of the drain.	In-progress
INV722153/7	Peanut Butter Plant: Roasting Room, Underside of metal plate covering E. Drain.	In-progress
INV722153/8	Peanut Butter Plant, Roasting Room, E. front leg of water heater located in the SE corner of the room.	In-progress
INV722153/9	Peanut Butter Plant, Roasting Room, Area next to the W. front leg of water heater in SE corner of room.	In-progress
INV722153/10	Peanut Butter Plant, Roasting Room, Bristles of red handled broom hanging on E. wall next to water heater.	In-progress
INV722153/11	Peanut Butter Plant, Roasting Room, Bristles of red handled large push broom hanging on E. wall next to water heater.	In-progress
INV722153/12	Peanut Butter Plant, Roasting Room, Bristles of second red handled broom hanging on E. wall next to water heater.	In-progress
INV722153/13	Peanut Butter Plant, Roasting Room, Area under compressor located just W of water heater.	S. Senftenberg

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Sample/Sub#	Location –Peanut Butter Plant	Salmonella Type
INV722153/14	Peanut Butter Plant, Roasting Room, Floor area around N. support bracket of compressor.	S. Senftenberg
INV722153/16	Peanut Butter Plant, Roasting Room, 3 rd Roaster leg from E raw entrance of the roaster on S side of room.	S. Montevideo
INV722153/21	Peanut Butter Plant, Roasting Room, Gap between floor and S wall ~ 1 ft W of red line.	S. Bredeney
INV722153/56	Peanut Butter Plant, Roasting Room, Top cover of screw conveyer that carries peanuts to the three bins in roasting room.	S. Bredeney
INV722153/61	Peanut Butter Plant, Roasting Room, Bristles of green handled push broom hanging on the W. wall next to entrance door and warehouse door.	S. Bredeney
INV722153/62	Peanut Butter Plant, Roasting Room, Bristles of green handled push broom hanging on the W. wall next to the entrance door and warehouse door.	S. Mbandaka
INV722153/73	Peanut Butter Plant, Roasting Room, Main center hopper middle support leg, closest to S wall.	S. Mbandaka
INV722153/74	Peanut Butter Plant, Roasting Room, NW support leg blancher b(4)	S. Montevideo
INV722155/230	Peanut Butter Plant: Packaging Room, NE support leg of b(4) filler.	In-progress
INV722155/296	Peanut Butter Plant: Machine Room, Floor beneath cooling b(4) pipes S. of the NH3 tank.	In-progress
INV722156/315	Peanut Butter Plant: Raw Room, Wheel of automated lift found in raw room.	S. Mbandaka
INV722156/331	Peanut Butter Plant: Raw Room, Bristles of Red handled broom in the	S. Meleagridis

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Peanut Butter Manufacturer

Sample/Sub#	Location –Peanut Butter Plant	Salmonella Type
	SE corner of Raw Peanut Receiving Room.	

Sample/Sub#	Location –Peanut Plant	Salmonella Type
INV722156/400	Peanut Plant, Roasting Room, Floor junction middle of cement filled area (where a wall used to be).	S. Anatum
INV774961/429	Peanut Plant, Picking Room, Weld area of metal plate just above b(4) pick line in picking room.	In-progress
INV774961/431	Peanut Plant, Picking Room, Pick room vacuum.	In-progress
INV774961/465	Peanut Plant, Production Room, Floor area on NW corner of scale platform located under shelled jumbo tank hopper.	In-progress
INV774961/482	Peanut Plant, Salt/Bringing Room, Handle attached to top of brine basket.	In-progress

OBSERVATION 2

Failure to handle equipment, containers and utensils used to convey, hold, and store food in a manner that protects against contamination.

Specifically,

- A. Specifically, the production and packaging lines of equipment in the Peanut Butter Plant were not cleaned after each time Salmonella was isolated from peanut and nut butter products between 2009 and 2012.
 - i. There are no records to document the cleaning of the production and packaging lines after

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Portales, NM 88130	Peanut Butter Manufacturer	

Salmonella was detected in peanut and nut butters between 2009 and 2012.

- B. The **b(4)** brand packaging equipment in the small packaging room of the Peanut Plant is not effectively cleaned between raw and roasted peanuts. Cleaning consists of wiping off non-food contact surfaces with dry paper towels, sweeping underneath and around equipment, as well as vacuuming excess dust.
- C. **b(4)** tote mesh bags utilized by your firm for storing bulk peanuts are not effectively cleaned between storage of raw and treated (roasted and/or brined) peanuts. The tote bags are considered multi-use, and re-used for both raw and roasted peanuts.
- i. The totes are cleaned by compressed air to loosen and remove dust/soil.
 - ii. We observed tote bags filled with raw peanuts transported from the Peanut Plant by truck bed into the raw room of the Peanut Butter Plant.
 - iii. The tote bags are not labeled for raw or roasted peanuts. The tote bags are labeled with the statement "FOR PEANUTS ONLY".
- D. Your firm does not clean production and packaging equipment between runs of various allergen containing products. Your firm utilizes a **b(4)** **b(4)** before packaging.

Your firm performs allergen testing on finished product at least **b(4)** and has detected allergens (peanut, almond, and soy) above **b(4)** ppm in a variety of butter products that do not contain those ingredients on the labeling. These products were also distributed by your firm.

For example,

- i. on 10/31/11, peanut allergens greater than **b(4)** ppm were detected in almond butter after **b(4)** **b(4)** of production
- ii. on 7/13/12, soy allergens were detected in almond butter at **b(4)** ppm after **b(4)** of production
- iii. on 8/24/12, almond allergens at greater than **b(4)** ppm were detected in peanut butter after **b(4)** of production

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Peanut Butter Manufacturer

Additionally, In May 2011, your firm received notification of a complaint that a child experienced anaphylactic shock after ingesting almond butter that contained peanut allergens.

OBSERVATION 3

Food contact surfaces used for manufacturing low-moisture food were wet at time of use.

Specifically,

On 9/26/12, in the small packaging room of the Peanut Plant, we observed an employee on the **b(4)** packaging line cleaning a food-contact belt with a spray bottle containing only water. The Peanut Plant Manager stated that the water was to be used on non-food contact surfaces of the packaging equipment.

OBSERVATION 4

The design and workmanship of equipment does not allow proper cleaning.

Specifically,

- A. Specifically, on 9/25/12, we observed a portion of the gasket improperly seated. The gasket is used to seal the lower portion of the **b(4)** and **b(4)** the visible portion extending from the **b(4)** appeared torn. Product residue was observed on and around this gasket as well as on the gasket seal located on the upper portion of the mill. The **b(4)** is used to grind peanuts into peanut butter and is located in the Mill/Grinding Room of the Peanut Butter Plant.
- B. On 09/25/2012, we observed dead legs on processing equipment in the Peanut Butter Plant:
 - i. A pipe connection approximately three inches long located on the Northwest corner of **b(4)** "in-flow" hopper. This connection was not piped to any equipment and was closed with a tri-clamp and lid, and allows food material to accumulate.
 - ii. A pipe approximately 4 feet long was attached to the **b(4)** line **b(4)**. The Production Supervisor explained that this **b(4)** specific peanut butter products. **b(4)** when

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- b(4)** is not added, nut butter may backflow into the **b(4)** pipe extension.
- iii. A pipe containing two tri-clamp rings was connected to the 45 degree pipe connection on the **b(4)** line **b(4)** "in-flow" pipe. This pipe was not connected to any other machinery and allows food material to accumulate.
- iv. The "T" pipe, connected to the "out-feed" line of the **b(4)** line heat exchanger, **b(4)** contains a dead end at the peanut butter flow sensor and allows food material to accumulate.
- v. A pipe connection approximately 2 inches long was observed located on the return pipe connected to the **b(4)** line filler. The connection is closed with a tri-clamp and lid and allows food material to accumulate.
- vi. The **b(4)** filler hopper contains a pipe connection near the bottom of the hopper. This connection is closed with a tri-clamp and lid. Additionally, the firm Production Supervisor stated that the filler has not been used for at least three months, but the pipe connector still contained peanut butter.

OBSERVATION 5

Failure to have smoothly bonded or well maintained seams on food contact surfaces, to minimize accumulation of food particles, dirt, and organic matter and the opportunity for growth of microorganisms.

Specifically,

- A. On 9/25/12, we observed an uneven weld on the northeast, inner corner of the hopper located at the picking table for the **b(4)** Line in the Mezzanine of the Mill/Grinding Room of the Peanut Butter Plant. The weld was not smooth to facilitate cleaning and sanitizing. Roasted, shelled peanuts fall into the hopper and are transferred to the first floor of the room for addition into peanut butter as needed.
- B. On 9/26/12, we observed an uneven weld under the metal cover located after the filler and before the capping machine on the **b(4)** Line in the Filling/Packaging Room of the Peanut Butter Plant. The weld was not smooth to facilitate cleaning and sanitizing. Open containers with product travel directly under the covers as they are conveyed to the capping machine.

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C. On 9/27/12, we observed an uneven weld on the northwest, inner corner of the hopper located below the cleaner discharge chute in the Raw Room of the Peanut Butter Plant. The weld was not smooth to facilitate cleaning and sanitizing. Cleaned, shelled peanuts fall into this hopper
b(4)

OBSERVATION 6

Employees did not wash hands thoroughly in an adequate hand-washing facility at any time their hands may have become soiled or contaminated.

Specifically,

- A. On 9/17/12, we observed an employee in the Mill Room of the Peanut Butter Plant handling and pouring soy protein powder into the production equipment for almond butter. Between handling soy protein powder bags and performing other duties in the Mill Room, he was observed repeatedly wiping his gloved hands on his street clothes. The employee did not wash his hands or change his gloves after wiping his hands on his clothes.
- B. The Peanut Plant does not have any hand washing sinks in the production or packaging areas. The building is equipped with hand sanitizer stations in the production and packing rooms.
 - i. On 9/28/12, we observed five employees having bare hand contact with ready to package, in-shell peanuts in the Picking Room of the Peanut Plant. The closest handwashing sink is located in the employee break room, behind closed doors, and approximately 200-400 feet away from production and packaging areas.

OBSERVATION 7

Plumbing is not adequately installed and maintained to properly convey sewage and liquid disposable waste from the plant.

Specifically,

On 9/22/12, during a tour of the Peanut Butter Plant, we observed the three compartment sink in the

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wash room adjacent to the mill room to be leaking, with water accumulating onto the floor and draining towards the floor drain. The floor drain was approximately 15 feet away from the three compartment sink.

OBSERVATION 8

The plant is not constructed in such a manner as to allow floors, walls, and ceilings to be adequately cleaned and kept clean and kept in good repair.

Specifically,

- A. On 9/26/12, we observed a 1x4 inch piece of wood approximately 1 foot long in a drain located in the middle of the Filling/Packaging Room of the Peanut Butter Plant. The drain is not used and was filled with concrete. The wood was placed vertically along the north end of the drain against the concrete. Wood is not an easily cleanable surface.
- B. The walls in the Cleaning Room, Picking Room, and Sheller Room of the Peanut Plant are not easily cleanable. The surface is comprised of "chicken" wire fencing material, and insulation with a plastic overwrap. The walls in these areas were observed with an accumulation of dust, and torn/exposed insulation.

OBSERVATION 9

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

Specifically,

- A. From 9/17/12-10/2/12, raw, in-shell peanuts were observed outside in uncovered trailers and open to the elements. Birds too numerous to count were observed flying over, and landing on peanuts in the trailers.
- B. On 9/28/12, we observed the weather as overcast and rainy, seven open trailers filled with peanuts were observed stored uncovered on the front of your property exposed to moisture from

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the weather.

OBSERVATION 10

Effective measures are not being taken to exclude pests from the processing areas.



Specifically,

- A. On 9/26/12, we observed the Roasting Room roll up door of the Peanut Plant was open to the outside with a plastic strip curtain hanging down in the door frame. The Peanut Plant Manager explained that the roll-up door remains open during processing, which can be as long as **b(4)** per day to allow fork lift access. The roll-up door is approximately 20 feet away from the in-shell peanut roaster oven. The end of the roaster where roasted peanuts are dropped onto a vibrating conveyor is open to the environment.
- B. On 9/28/12, we observed one bird-like excreta dropping on one pallet of (Product ID 900251) almond butter in 16 oz containers, with manufacture date August 23rd, 2012 in the Peanut Butter Plant warehouse.

*** DATES OF INSPECTION:**

09/17/2012(Mon), 09/18/2012(Tue), 09/19/2012(Wed), 09/20/2012(Thu), 09/21/2012(Fri), 09/22/2012(Sat), 09/23/2012(Sun), 09/24/2012(Mon), 09/25/2012(Tue), 09/26/2012(Wed), 09/27/2012(Thu), 09/28/2012(Fri), 09/29/2012(Sat), 09/30/2012(Sun), 10/01/2012(Mon), 10/02/2012(Tue), 10/04/2012(Thu), 10/15/2012(Mon), 10/16/2012(Tue)

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jamie L. C. Dion, Investigator  Brent W. Higgs, Investigator Daniel J. Lahar, Investigator Isabel Y. Espinosa, Investigator  Gloria A. Milster, Investigator Edith M. Gonzalez, Investigator	DATE ISSUED 10/29/2012
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