Establishment Inspection Report	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

## TABLE OF CONTENTS

Summary	1
Administrative Data	3
History	4
Interstate Commerce	4
Jurisdiction	5
Individual Responsibility and Persons Interviewed	5
Firm's Training Program	7
Manufacturing/Design Operations	7
Manufacturing Codes	9
Complaints	
Recall Procedures	9
Objectionable Conditions and Management's Response	9
Refusals	16
General Discussion with Management	16
Additional Information	16
Samples Collected	17
Voluntary Corrections	17
Exhibits Collected	18
Attachments	19

# SUMMARY

This comprehensive inspection of Sunland, Incorporated, an in-shell and shelled peanut processor and nut butter manufacturer, was conducted as part of the Denver District FY' 11 work plan per FACTS assignment 1214621 and was performed in accordance with the Domestic Food Safety Compliance Program (CP 7303.803) and the BSE/Ruminant Feed Ban Compliance Program (CP 7371.009).

The previous FDA inspection was conducted 09/21-23/10 and was classified VAI. A Form FDA-483 Inspectional Observations was issued to the firm for the following observations:

- 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 pest from the processing areas and protect against the contamination of food on the premises by pest;

<b>Establishment Inspection Report</b>	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

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

Management agreed with the observations and promised to address and correct all issues.

During the current inspection, the firm was actively storing, processing, and packaging raw inshelled peanuts. Raw product receipt, grading, drying, storage, manufacturing, packaging and distribution as well as pest control, recalls, sanitation, and complaints were covered during this inspection. A Form FDA-483, Inspectional Observations, was issued to Mr. Jimmie D. Shearer, President and CEO, at the conclusion of the inspection for the following:

- 1. Failure to store raw materials in a manner that protects against contamination;
- 2. Failure to provide adequate screening or other protection against pests;

Mr. Jimmie D. Shearer agreed with the observations and promised to address and correct all issues. He stated the firm planned to address the observations in a written response to the Denver District Director within 15 business days.

Samples were taken during the course of the inspection and consisted of two product samples. One sample was analyzed for Salmonellae (681978) and one sample was analyzed for Filth (681981).

A reconciliation examination was not conducted during the inspection. A label field examination was conducted during the inspection. No refusals were encountered during the course of this inspection.

#### b) (3) (A)

All post-inspectional correspondence, including FMD-145 information, should be addressed to Mr. Jimmie D. Shearer, President and CEO, Sunland, Incorporated, P.O. Box 1059, Portales, NM 88130.

Establishment Inspection Report	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

#### ADMINISTRATIVE DATA

Inspected firm:	Sunland, Incorporated
Location:	42593 US Highway 70
	Portales, NM 88130-9043
Phone:	575-356-6638
FAX:	575-356-6630
Mailing address:	P.O. Box 1059
	Portales, NM 88130
Dates of inspection:	3/23/2011, 3/24/2011, 3/25/2011
Days in the facility:	3
Participants:	Felix J. Marrero, Investigator Isabel Y. Espinosa, Investigator

This inspection was conducted by CSO Isabel Y. Espinosa, and me, CSO Felix J. Marrero. I served as the lead for the inspection and was responsible for writing the entire report.

On 03/23/11, CSO Espinosa, and I presented our credentials to Ms. Toni G. Williamson, Accounting Supervisor, and issued a Form FDA-482, Notice of Inspection, to her. Ms. Williamson stated she was the most responsible person at the firm as management personnel were all out for lunch at the time. On 03/23/11, CSO Espinosa, and I presented our credentials to Mr. Paul W. Newsom, Executive Vice President, and issued a new Form FDA-482, Notice of Inspection upon his return to the office. He stated he was the most responsible person at the firm as the President and CEO would not be in the office until later that day. The second Form FDA-482, Notice of Inspection, was issued to Mr. Paul W. Newsom, due to his position as part of the firm's top management.

On 03/25/11, a Form FDA-463a, Affidavit, was signed by Mr. Jimmie D. Shearer, President and CEO, regarding the receiving, drying, and interstate shipment of Sunland Valencia Kissed by the Sun Raw Valencia Peanuts lot number 19. The affidavit and copies of all related documents are included in Sample #DOC681982. At the conclusion of the inspection, a Form FDA-483, Inspectional Observations, was issued to Mr. Jimmie D. Shearer, President and CEO, regarding observations related to raw material storage and screening or other protection against pests. A general discussion was also held with Mr. Jimmie D. Shearer and management at that time.

At the close of the inspection on 03/25/11, a Form FDA-484, Receipt for Samples, was issued to and signed by Mr. Jimmie D. Shearer, President and CEO, documenting samples 681978 and 681981 obtained from the firm.

Establishment Inspection Report	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

An amended Form FDA-483, Inspectional Observations, was issued to Mr. Jimmie D. Shearer, President and CEO, at the close of the inspection on 03/25/11. An error was noted after the original Form 483 had been issued to Mr. Shearer but before we left the facility. In Observation #1, the barn number was incorrectly listed. The barn number where the peanuts had been removed was listed as  $barn^{(b)}_{(4)}$  instead of  $d^{(b)}(4)$ 

# HISTORY

Sunland, Incorporated is located at 42593 US Highway 70, Portales, NM 88130. The firm is on 70 acres of land owned by Sunland, Incorporated. This is the sole location for the firm. The firm was incorporated in 1988 in Santa Fe, New Mexico.

According to Mr. Paul W. Newsom, office hours are 8 a.m. to 5 p.m. Monday through Friday. (b) (4)

(b) (4)	The firm has approximately <sup>(b)</sup> employees. However, during
the harvest season, <sup>(b) (4)</sup>	Harvest season occurs from mid
(b) (4)	depending on the weather conditions.

# (b) (3) (A)

(b) (3) (A) We provided Mr. Jimmie M. Shearer with a copy of FDA's *What You Need to Know About Registration of Food Facilities*. A copy of the ALERT card and *Guidance for Industry Food Producers, Processors, and Transporters Food Security Preventive Measures Guidance* was provided and discussed with the firm. The FDA Reportable Food Registry was also discussed with the firm and the *Reportable Food Registry (RFR): At A Glance* was provided.

All post-inspectional correspondence, including FMD-145 information, should be addressed to Mr. Jimmie D. Shearer, President and CEO, Sunland, Incorporated, P.O. Box 1059, Portales, NM 88130.

# INTERSTATE COMMERCE

Sunland, Incorporated's top three suppliers of raw peanuts are  $^{(b)}$   $^{(4)}$ 

Approximately<sup>(b) (4)</sup> of the firm's finished products are shipped out of state to distributors. The top distributors the firm sells product to are<sup>(b) (4)</sup>

```
The firm also exports its products to<sup>(b) (4)</sup>
```

(b) (4)

Establishment Inspection Report	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

The firm sells approximately<sup>(b) (4)</sup> of its products wholesale. Some finished products are sold at their Sunland's Retail Store located on the same property as the firm and through their website (www.sunlandinc.com).

# JURISDICTION

Sunland, Incorporated is a dual jurisdiction firm. The United States Department of Agriculture (USDA) contracts with the New Mexico Department of Agriculture (N.M.D.A.) to perform grading of incoming peanuts and processed finished product. Neither USDA nor N.M.D.A. agents were present during the current inspection.

Sunland, Incorporated Plant manufactures and packs a variety of in-shell peanuts, shelled peanuts, and nut butters. Sunland, Incorporated's products are sold under multiple private labels to include: Sunland, Naturally More, (b) (4) Sprouts, and Harry & David. A list of products manufactured and sold by the firm was provided during the inspection (Exhibit 2).

Finished product labels were collected and reviewed for the following products:

- 1. Sunland CREAMY PEANUT BUTTER NET WT. 18 OZ. (Exhibit 3)
- 2. SUNLAND Natural Peanut Butter Net Weight 16 oz. (Exhibit 3)
- 3. SUNLAND RAW VALENCIA PEANUTS 16 oz. (Exhibit 3)

# INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

# Mr. Jimmie D. Shearer, President and CEO

Mr. Jimmie D. Shearer is the President and CEO and identified himself as the most responsible individual at the firm. Mr. Shearer oversees all operations, has the ultimate responsibility, power, and duty to correct and prevent objectionable conditions. Mr. Shearer has the authority to make financial decisions, hire and terminate individuals with Human Resources involvement, and stop production if an issue arises. Mr. Shearer has been with the company since 1991 and in his current role as President and CEO since 1993. Mr. Shearer reports to the Board of Directors and to the Members of the Board. Mr. Shearer provided information regarding the firm, purchasing, processing, receiving, and shipping of products.

Establishment Inspection Report	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

#### Mr. Paul W. Newsom, Executive Vice President

Mr. Paul W. Newsom is the Executive Vice President and has the authority, power, and duty to correct and prevent objectionable conditions. Mr. Newsom has the ultimate responsibility for all raw goods, production, and finished product activities at the firm. Mr. Newsom has oversight for all the purchasing and sells activities for both the peanut and nut butter divisions of the firm. Mr. Newsom has the authority to make financial decisions with the approval of Mr. Jimmie D. Shearer, President and CEO of the firm. Mr. Newsom has the authority to hire and terminate individuals with Human Resources involvement, and stop production if an issue arises. Mr. Newsom has been with the company for over 22 years and in his current role as Executive Vice President for the last 12 years. Mr. Newsom supervises both the peanut and peanut butter production managers' and reports to Mr. Jimmie D. Shearer, President and CEO of the firm. Mr. Newsom provided information regarding the firm, purchasing, processing, receiving, and shipping of products.

## Ms. Samantha Rector, Quality Control Supervisor

Ms. Samantha Rector is the Quality Control Supervisor and has the authority, power, and duty to correct and prevent objectionable conditions. Ms. Rector is responsible for the quality in the production of peanuts and nut butter products. Ms. Rector is not authorized to make financial decisions but can hire or terminate employees with Human Resources involvement, and stop production if an issue arises. Ms. Rector has been with the firm for 11 years and in her current position as Quality Control Supervisor for the last seven years. Ms. Rector supervises <sup>(b) (4)</sup> employees and reports to Messrs. Jimmie D. Shearer, President and CEO and Paul W. Newsom, Executive Vice President. Ms. Rector was present during a tour of the facility and was also present during sampling of product conducted by CSO Espinosa and me.

# Mr. Mark B. Bruffett, Peanut Production Plant Manager

Mr. Mark B. Bruffett is the Peanut Production Plant Manager and has the authority, power, and duty to correct and prevent objectionable conditions. Mr. Bruffett is responsible for all peanut production activities, receiving, and shipping of product. Mr. Bruffett is not authorized to make financial decisions but can hire or terminate employees with Human Resources involvement, and stop production if an issue arises. Ms. Bruffett has been with the firm for 15 years and in his current position as Peanut Production Plant Manager for the last six years. Mr. Bruffett supervises four employees and reports to Messrs. Jimmie D. Shearer, President and CEO and Paul W. Newsom, Executive Vice President. Mr. Bruffett provided a tour of the area where the drying of in-shell peanuts occurs, the Peanut Production Plant, and shipping and receiving areas. Mr. Bruffett was also present during sampling of product conducted by CSO Espinosa and me.

<b>Establishment Inspection Report</b>	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

#### Mr. Weston L. Pierce, Peanut Butter Plant Manager

Mr. Weston L. Pierce is the Peanut Butter Plant Manager and has the authority, power, and duty to correct and prevent objectionable conditions. Mr. Pierce is responsible for all operations related to the production of nut butters. Mr. Pierce is authorized to make financial decisions related to production, can hire or terminate employees with Human Resources involvement, and stop production if an issue arises. Mr. Pierce has been with the firm and in his current position as Peanut Butter Production Plant Manager for the last 10 years. Mr. Pierce supervises an Assistant Manager and <sup>(b) (4)</sup> Production Supervisors. Mr. Pierce reports to Messrs. Jimmie D. Shearer, President and CEO and Paul W. Newsom, Executive Vice President. Mr. Pierce provided a tour of the Peanut Butter Production Plant, and shipping and receiving areas.

#### Ms. Toni G. Williamson, Accounting Supervisor

Ms. Toni G. Williamson has been with the firm and in her current position for the last 15 years. Ms. Williamson answers to Mr. Ruddy Pearce, the firms Comptroller. Ms. Williamson was issued a Form FDA-482, Notice of Inspection, Ms. Williamson stated she was the most responsible person at the firm as the President and CEO of the firm was not present.

# FIRM'S TRAINING PROGRAM

The firm's new hire training is conducted as part of the employee orientation and consists of Human Resources and Good Manufacturing Practices. <sup>(b) (4)</sup> training is also conducted and documented in the employee's personnel folder. All training conducted is tracked on a spreadsheet by the firm.

# MANUFACTURING/DESIGN OPERATIONS

Sunland, Incorporated consists of outside peanut <sup>(b)</sup> <sup>(4)</sup> railers, multiple warehouses that store unprocessed peanuts, peanut processing facility, nut butter processing facility, storage facility, warehouse, office space, and a store front. All processes, including drying, manufacturing, packaging, storage, and shipping, occur at this facility.

The firm was actively storing, processing, and packaging peanut products during the current inspection. Mr. Bruffett provided a tour of the entire raw in-shell peanut process. <sup>(b) (4)</sup>

(b) (4)		The firm starts its harvest
season in <sup>(b) (4)</sup>		depending on the weather
conditions. (b) (4) (b) (4)	 , i	

<b>Establishment Inspection Report</b> Sunland, Incorporated Portales, NM 88130-9043	FEI: EI Start: EI End:	<b>1000117188</b> 03/23/2011 03/25/2011
(b) (4) (c) (4) trailers are taken to the scale to be weighed. Then the	a popula are graded by the N	the MDA and a
<ul> <li>sample is taken for Aflatoxin by the N.M.D.A. Once they are stored in one of the firm's<sup>(b)</sup> storage barns v bins<sup>(b) (4)</sup></li> <li>(b) (4)</li> <li>(b) (4)</li> <li>(b) (4)</li> <li>(b) (4)</li> <li>Th</li> </ul>	the peanuts have passed the within (b) (4) All peanuts and the peanuts then go through an	N.M.D.A. grading, will be placed into
process to remove debris. Then the in-shell peanuts e which removes dirt, rocks, and sticks from the peanuts (b) (4)		
(b) (4) (c) (4) The in-shell oz, and 16 oz ploy-film bags.	ll raw peanuts are packaged i	n 2 oz, 4 oz, 12

Establishment Inspection Report	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

#### MANUFACTURING CODES

The manufacturing code consists of three rows of a digital stamp containing letters and numerical characters (see Figure 1). The top row states "Best by", the second row represents the month, day, and year that the product is good for. For example, a "Best by" code of "MAR 10 2012" represents March 10, 2012. The bottom row represents <sup>(b) (4)</sup>

Figure 1.

#### COMPLAINTS

All complaints for the firm are received by either Quality Control or Customer Service and referred to a consultant to be resolved. The consultant sends a <sup>(b) (4)</sup> complaint report to the firm.

#### **RECALL PROCEDURES**

The firm has not recalled a product since the last inspection. In the event of a recall, Mr. Shearer would be the point of contact for the firm as well as the firm's Crisis Management Team. The firm conducts mock recalls at least<sup>(b) (4)</sup> All mock recall scenarios are developed by Mr. Newsom and executed by the Quality Control Management.

#### **OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**

#### **Observations listed on form FDA 483**

#### **OBSERVATION 1**

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

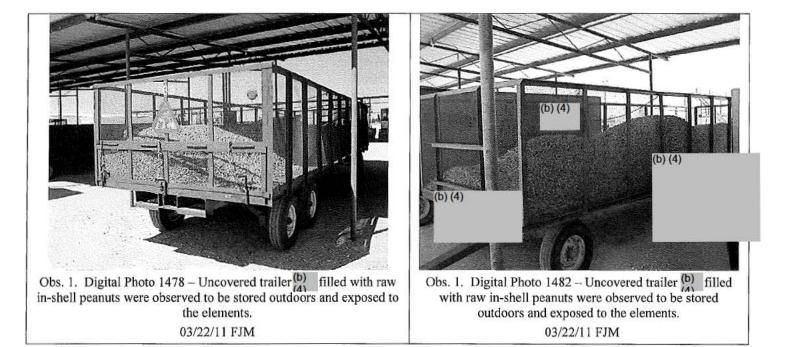
Specifically, on 3/23/11, uncovered trailers (b) (4) filled with raw in-shell peanuts were observed to be stored outdoors and exposed to the elements. These raw in-shell peanuts came from under the conveyer belt during a cleanout of Barn (b) Birds too numerous to count were observed flying over and landing on the in-shell peanuts. Apparent bird excrete also was observed on some of the in-shell peanuts. Management stated that these in-shell peanuts would be processed into shelled peanuts.

Establishment Inspection Report	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

Reference: 21 CFR 110.80(a)(1)

Supporting Evidence and Relevance:

This observation was cited for the failure to store raw in-shell peanuts in a manner that protects against contamination. The raw in-shell peanuts, located at 42593 US Highway 70 Portales, NM 88130-9043, were stored in uncovered trailers <sup>(b) (4)</sup> and were observed to have birds too numerous to count flying over and landing on the in-shell peanuts. Apparent bird excreta was observed on some of the exposed peanuts. Adequate screenings needs to be in place to protect against contamination.



# Establishment Inspection Report

Sunland, Incorporated Portales, NM 88130-9043

FEI:	1000117188
EI Start:	03/23/2011
EI End:	03/25/2011



Obs. 1. Digital Photo 1480 – Raw in-shell peanuts from under the conveyer belt during a cleanout of Barn (b) tored outside uncovered. 03/23/11 FJM



Obs. 1. Digital Photo 1483 – Uncovered trailer (b) with raw in-shell peanuts were observed to be stored outdoors and exposed to the elements. 03/23/11 FJM



Obs. 1. Digital Photo 1498 – Uncovered trailer<sup>(b)</sup> filled with raw in-shell peanuts were observed to be stored outdoors and exposed to the elements. 03/23/11 FJM

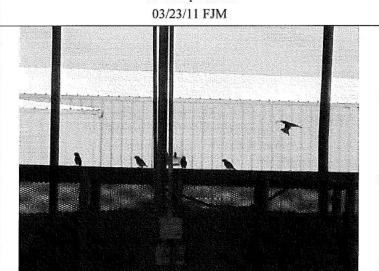


Obs. 1. Digital Photo 1486 – Raw in-shell peanuts from under the conveyer belt during a cleanout of Barn(4) outside uncovered. 03/23/11 FJM

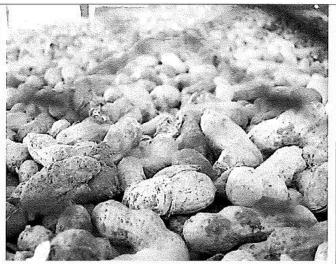
Establishment Inspection Report	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011



Obs. 1. Digital Photo 1485 – Raw in-shell peanuts from under the conveyer belt during a cleanout of Barn<sup>(b)</sup> stored outside uncovered. Apparent bird excreta also was observed on some of the in-shell peanuts.



Obs. 1. Digital Photo 1518 – Birds too numerous to count were observed flying over and landing on the in-shell peanuts stored outside uncovered. 03/23/11 FJM



Obs. 1. Digital Photo 1497 – Raw in-shell peanuts from under the conveyer belt during a cleanout of Barn<sup>(b)</sup> stored outside uncovered. Apparent bird excreta also was observed on some of the in-shell peanuts.

03/23/11 FJM



Obs. 1. Digital Photo 1519 – Birds too numerous to count were observed flying over and landing on the in-shell peanuts stored outside uncovered. 03/23/11 FJM

Establishment Inspection Report	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

Discussion with Management:

This was brought to the attention of Mr. Shearer and management during the inspection and again during the close-out meeting. During the close-out discussion, Mr. Shearer agreed with the observation and stated that he thought the peanuts had been processed or that the trailers had covers over them. Also, Mr. Shearer stated that since he is now aware of the peanuts still being uncovered, the exposed raw in-shell peanuts would be removed from the trailers on the afternoon of 03/25/11.

#### **OBSERVATION 2**

Failure to provide adequate screening or other protection against pests.

Specifically,

a. On 3/23/11 - 3/24/11, the plastic strip door curtain located at the north production warehouse dock door was missing a strip. Raw product is stored approximately 20 feet from the plastic strip door curtain.

b. On 3/23/11, three gaps were observed on the exit door on the southwest portion of the loading dock, and located approximately 6 feet from finished product. The first gap approximately 1/2 inch wide by 1 inch high, was observed under the southwest portion of the door. The second gap approximately 1/2 inch wide by 1 inch high, was observed under the northwest portion of the door. The third gap approximately 1/4 inch wide by 7 feet high, was observed along the northern side of the door frame.

c. On 3/24/11, two gaps were observed on the south dock door in the peanut butter cleaning room, and located approximately 12 feet from raw product. The first gap approximately 1/2 inch wide by 10 feet high, was observed along the north side of the dock door. The second gap approximately 1/4 wide by 3 feet high, was observed along the south side of the dock door.

Reference: 21 CFR 110.20(b)(7)

Supporting Evidence and Relevance:

# **Establishment Inspection Report**

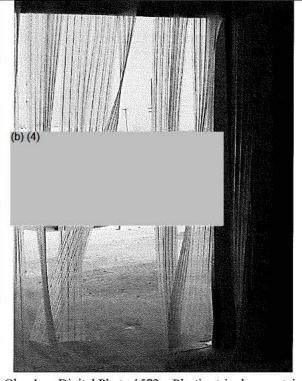
Sunland, Incorporated Portales, NM 88130-9043

(b) (4)	

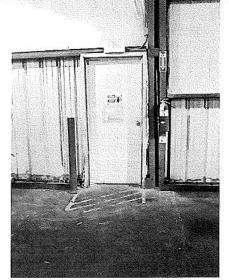
Obs. 1.a. Digital Photo 1571 – Plastic strip door curtain located at the north production warehouse dock door was missing a strip. Raw product is stored approximately 20 feet from the plastic strip door curtain.

03/24/11 FJM

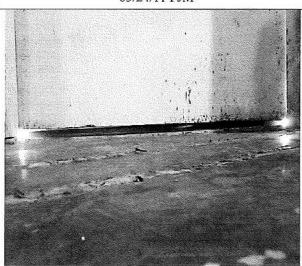
FEI: EI Start: EI End: **1000117188** 03/23/2011 03/25/2011



Obs. 1.a. Digital Photo 1572 – Plastic strip door curtain located at the north production warehouse dock door was missing a strip. Raw product is stored approximately 20 feet from the plastic strip door curtain. 03/24/11 FJM



Obs. 1.b. Digital Photo 1525 – Three gaps were observed on the exit door on the southwest portion of the loading dock, and located approximately 6 feet from finished product. 03/23/11 FJM



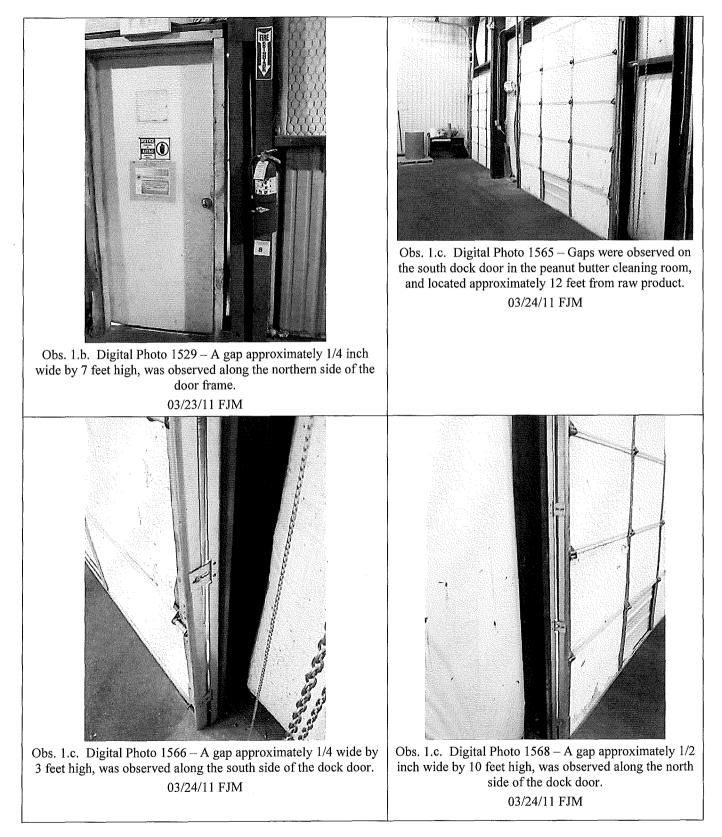
Obs. 1.b. Digital Photo 1528 - A gap approximately 1/2 inch wide by 1 inch high, was observed under the southwest portion of the door. A gap approximately 1/2 inch wide by 1 inch high, was observed under the northwest portion of the door.

03/23/11 FJM

# **Establishment Inspection Report**

Sunland, Incorporated Portales, NM 88130-9043

FEI:	1000117188
EI Start:	03/23/2011
EI End:	03/25/2011



Establishment Inspection Report	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

Discussion with Management:

This was brought to the attention of Mr. Shearer and management during the inspection and again during the close-out meeting. During the close-out discussion, Mr. Shearer agreed with all the observations and stated the firm had corrected the issue with the plastic strip door curtain on 03/25/11. He also stated that Mr. Bruffett would be working with the Maintenance Department to put a strip on the bottom of the curtain to control the flaps from swinging apart. Mr. Bruffett stated the firm had received the parts to correct the issue with the exit door on the southwest portion of the loading dock. Mr. Shearer stated that the issue with the south dock door in the peanut butter cleaning room would be corrected within the next couple of weeks.

#### REFUSALS

No refusals were encountered during the current inspection.

## GENERAL DISCUSSION WITH MANAGEMENT

At the conclusion of the inspection, a close-out meeting was held with Mr. Shearer and management. A Form FDA-483, Inspectional Observations, was issued to Mr. Shearer and discussed. At the conclusion of the meeting, I explained to the firm the sanctions available to the FDA if serious conditions are not voluntarily corrected.

# ADDITIONAL INFORMATION

#### **Pest Control**

The firm's pest services contractor conducts<sup>(b) (4)</sup> nonitoring. After each visit the pest control contractor provides an invoice to the Quality Control department to be reviewed and filed. If an issue arises a corrective action will be implemented to correct the issue. The majority of pest control activities are conducted before the harvest season.

Water/Waste

Water services are provided to the facility by  $^{(b)}$  (4) and is picked up  $^{(b)}$  (4)

A compactor is used for waste

#### **Reconciliation Exam**

A reconciliation examination was not conducted during the inspection.

Establishment Inspection Report	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

#### SAMPLES COLLECTED

A documentary sample (DOC 681982) was collected and contains forms that document the purchase, grading, drying, storing, testing, and distributing of Sunland's Kissed by the Sun Raw Valencia Peanuts. The documentary sample also consists of a Form FDA-463a, Affidavit, which was signed by Mr. Jimmie D. Shearer on 03/25/11.

During the current inspection, two samples of Sunland's Kissed by the Sun Raw Valencia Peanuts were collected. Sample 681978 was collected and analyzed for Salmonellae. Sample 681981 was collected and analyzed for Filth. All samples consisted of approximately 6-11b. subsamples of randomly collected raw in-shell Valencia peanuts from lot number 19. Each subsample was collected and placed in a sterile whirl-pak bag. After collection, the samples were placed in a cardboard box and delivered to the UPS Store in Clovis, NM for shipment to the FDA Denver District Laboratory for analysis.

# **VOLUNTARY CORRECTIONS**

During the previous inspection conducted 09/21-23/10, a Form FDA-483 was issued which documented five observations related to good manufacturing practices. I verified if all of the observations documented in the previous inspection were corrected by the firm within the agreed time frame provided by the firm. The observations listed in the previous inspection and addressed during the current inspection are as follows:

- 1. All reasonable precautions are not taken to ensure that production procedures do not contribute to contamination from any source. During the current inspection, the firm was only manufacturing peanut butter, so we were unable to observe the firm's cleanout procedure between the manufacturing of different products.
- 2. Effective measures are not being taken to exclude pest from the processing areas and protection against the contamination of food on the premises by pest.

2.1. During the current inspection, the rolling door again was observed not to be providing adequate screening.

2.2. During the current inspection, no live insects were observed in the Peanut Butter Plant.

- 3. *The plant is not constructed in such a manner as to allow floors to be kept in good repair.* During the current inspection, no issues were observed with the washroom floor in the production plant.
- 4. *Failure to wear bead covers in an effective manner*. During the current inspection, no issues were observed with employees wearing beard covers.

<b>Establishment Inspection Report</b>	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

5. The design and construction of equipment and utensils fail to preclude the adulteration of food with contaminations. During the current inspection, the device that was observed rusty in the previous inspection was not in use. Also, Mr. Pierce stated he was unaware of the device in question.

#### **EXHIBITS COLLECTED**

- Exhibit 1 Form FDA-525 containing disc of original digital photographs taken during the inspection, 1 page
- Exhibit 2 Product List, 7 pages
- Exhibit 3 Finished Product Labels, 3 pages
- Exhibit 4 Product Catalog, 8 pages
- Exhibit 5 Peanut Flow 5.1.1.2, 1 page
- Exhibit 6 Peanut Butter Flow 5.1.1.2 New Line, 2 pages
- Exhibit 7 Sunland, Inc. Organizational Chart, 1 page
- Exhibit 8 Truck Ticket with Load ID#: (b) (4) 1 page
- Exhibit 9 Invoice #: <sup>(b) (4)</sup> ated 10/09/10, 1 page
- Exhibit  $10 Drying Ticket \neq^{(b)} (4)$  dated 10/09/10, 1 page
- Exhibit 11 FV-95-CG Federal-State Inspection Service Peanut Inspection, U522869, 1 page
- Exhibit 12 Scale Ticket,<sup>(b) (4)</sup> 1 page
- Exhibit 13 FSA-1007 INSPECTION CERTIFICATE AND CALCULATION WORKSHEET, 0382855, 1 page
- Exhibit 14 Daily Production Sheets, Lot 19, 3 pages
- Exhibit 15 Daily Production Sheets, Lot 19, 2 pages
- Exhibit 16 FV-184-9A-CG MILLED PEANUT INSPECTION CERTIFICATE M0910586, Lot 19, 1 page
- Exhibit 17 Pack Out Sheet, dated 02/9-10/11, 1 page
- Exhibit 18 Manufacturing Order with Order No.:<sup>(b) (4)</sup> 1 page
- Exhibit 19 Pack Out Sheet, dated 03/03-17/11, 1 page
- Exhibit 20 Form 875 Grocery Products Purchase Order, dated 03/15/11, 1 page
- Exhibit 21 Picking List<sup>(b) (4)</sup> dated 03/15/11, 1 page
- Exhibit 22 SHIPPER-PROVIDED SHORT FORM BILL OF LADING<sup>(b) (4)</sup> 1 page
- Exhibit 23 Invoice<sup>(b) (4)</sup> 1 page
- Exhibit 24 Online ordering system printout, dated 03/22/11, 1 page

Establishment Inspection Report	FEI:	1000117188
Sunland, Incorporated	EI Start:	03/23/2011
Portales, NM 88130-9043	EI End:	03/25/2011

#### **ATTACHMENTS**

Form FDA-482, Notice of Inspection dated 03/23/11 Form FDA-482, Notice of Inspection dated 03/23/11 Form FDA-483, Inspectional Observations dated 03/25/11 Form FDA-483, Amendment 1 Inspectional Observations dated 03/25/11 Form FDA-484, Receipt for Samples dated 03/25/11 Form FDA-3719, BSE Report of Inspection

Felix J. Marrero, Investigator

Isabel Y. Espinosa, Investigator