DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION		
4040 North Central Expressway, Suite 300	02/04/2009 - 02/26/2009*		
Dallas, TX 75204	FEI NUMBER		
(214) 253-5200 Fax: (214) 253-5314	3005090079		
Industry Information: www.fda.gov/oc/industry	stry		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED			
TO: Mr. Roy V. Creasy, Jr., Trustee, US	Bankruptcy Court for the Western		
District of VA			
FIRM NAME	STREET ADDRESS		
Peanut Corporation of America (PCA)	3601 North I-27		
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED		
Plainview, TX 79073	Peanut Processor/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**

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, on 2/11-12/09, the following signs of rodent activity were observed.

- a) In a crawl like space between a false ceiling and the primary roof of the building other signs of rodent activity were observed. The false ceiling covered the kitchen/old lab rooms and the whole and split blanching processing areas. The ducting for the redskin removal (b) (4) (referred to as system was located in this area. The end cap of one of these ducts was open providing a passageway for rodents to access the blanching equipment below. Approximately 6 dead mice were found in this false ceiling area;
- b) A dead mouse stuck to a glue trap located at the wall/floor junction in the room off the west end of the kitchen/old lab rooms. The mouse appeared to have died recently;
- c) What appeared to be rodent excreta pellets (REP) were observed on the countertops of the south most room of the kitchen/old lab area;
- d) Unprotected possible rodent/pests entryways were observed at the ceiling/wall junction along the south and west walls next to the southwest corner of the mezzanine room;
- e) What appeared to be REPs too numerous to count were observed in the cabinet under the sink in the south most kitchen/old lab room;
- f) In the cabinet north of the dishwasher in the north most room of the kitchen/old lab rooms I counted approximately 27 REPs;
- g) More, what appeared to be REPs were observed in the cabinets under the bottom drawer in the south most room of the kitchen/old lab rooms; in an area 1" X 2" behind the bottom drawer in this cabinet I counted approximately 30 rodent excreta pellets;

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Plainview, TX 79073 Peanut Processor/Manufacturer		essor/Manufacturer	

- h) Another dead mouse was found just outside the south most doorway of the kitchen/old lab rooms at the east corner of the corridor leading from the mezzanine area into the kitchen/old lab rooms. This mouse also appeared to have recently died;
- i) What appeared to be a bird's nest was observed in the wall/ceiling metal support beam at southwest corner of the mezzanine area.

#### **OBSERVATION 2**

Failure to operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-contact surfaces, and food-packaging materials.

Specifically,

The b (4) filters (similar to the metal used on a cooking grill) of the air-makeup system were littered with feathers, lint, dust, and miscellaneous foreign debris. This observation was made on 2/11/09.

In this room where the air makeup equipment is housed, a strong negative pressure is created. This negative pressure had drawn redskins and other debris from the false ceiling area into the room. The false ceiling is also where significant signs of rodent activity were observed. A bed of redskins approximately 1" deep were accumulated on the floor of the air makeup room in the northwest corner.

The air-makeup system is designed to maintain a positive air pressure in the plant's peanut processing areas to prevent air infiltration from the raw peanut pre-clean processing areas. There was nothing to prevent the redskin and other foreign debris from being drawn into the air-makeup system and carried into the non-raw peanut processing environment via air inflow.

The room that houses the air-makeup system is located off the northwest corner of the mezzanine in the upstairs area.

#### **OBSERVATION 3**

Failure to clean food-contact surfaces as frequently as necessary to protect against contamination of food.

Specifically,

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On 2/9/09, at the following equipment food contact surface sites, an appreciable buildup of peanut fines, meal, chunks, or paste (some gooey other solidified) was observed:

## **Granulation Room Sites**

- a) Dump station discharge chute for elevator located on east wall of granulation;
- b) Intake chute of (b) (4) vibrator shaker located in the granulation room;
- c) Discharge chute of peanut meal bin in granulation room;
- d) Inside surface of bin feeding grinder at the discharge chute gate;

# **Processing Area**

- e) Inside rear surface of south feed for (b) (4) (camera sorting machine aka electric eyes) machine; nozzle #
- f) Inside rear surface of middle feed for (b) (4) (camera sorting machine aka electric eyes) machine; nozzle #
- g) Inside rear surface of north most feed for (b) (4) (camera sorting machine aka electric eyes) machine; identified as nozzle #
- h) Inside rear surface of south most feed for (camera sorting machine aka electric eyes) machine; identified as nozzle #
- i) West most cylindrical (approximately in diameter) roller of split blanching machine located at southeast corner of blanching processing area; top center of roller sponged;

## Oil Roasting Processing Area

- i) Accumulation of roasted peanut debris on oil roasters cooling tunnel conveyor belt:
- k) Southwest corner of hand-sorting conveyor belt beyond oil roaster's cooling tunnel; peanut debris collect at edge of belt underneath a 2" wide protective strip;
- 1) Inside surface of oil roaster's pack-off chute;
- m) Inside surface of peanut meal tote transfer funnel; accumulation of meal on chute rim and throughout the inside surfaces of the funnel;
- n) Inside surface at southwest corner of gravity table discharge chute; gravity table is located diagonally off the northeast corner of oven roaster;

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o) Inside wall at the southeast corner under lid of whole peanut blancher # (b) (4)

p) Inside west wall of the second section from the middle of whole peanut blancher #(b) (4)

q) Top stair plate (peanuts fall down as bin fills) inside east most bin feeding split blancher; peanut debris accumulated on corners of stair:

r) Split blancher discharge chute that dumps into vibrating conveyor;

# **Pre-clean Processing Area**

s) 90 degree turn of vibrating conveyor leading to elevator that feeds de-stoner holding bin; peanut debris accumulated in corners and jagged surfaces.

#### **OBSERVATION 4**

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

Specifically,

Roof leaks where rain water was observed dripping into the plant's peanut processing areas were observed at the following locations:

- a) Roof leaking in pre-clean area above the space between the gravity shaker and raw peanut tote dump station; leaking water was observed running down roof support pole on east side of raw peanut tote dump station;
- b) Roof leaking at overhead hanging doorway leading from pre-clean area to oven roasting area; the dripping water was landing on the top side of the opened (spooled) overhead hanging door; drip splatter could potentially contaminate the conveyor belt running near the ceiling from the pre-clean bins to the oven;
- c) Roof leaking in the hallway diagonal to the northeast of the doorway leading to oil roasting and granulation processing areas;
- d) Roof leaking in work in process (WIP) area and pooling on the floor between organic and oil-stock storage areas approximately 20' off oil-stock storage area's southwest door;
- e) Roof leaking in WIP area and pooling on the floor below between storage areas identified as "Q" and "R" approximately 1' west of "Q";
- f) Roof leaking in (WIP) area and pooling on the floor below between storage areas identified as "Q"

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Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314 (Industry Information: www.fda.gov/oc/indu (AME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  TO: Mr. Roy V. Creasy, Jr., Trustee, US (District of VA) (IRM NAME) (Peanut Corporation of America (PCA) (ITY, STATE, ZIP CODE, COUNTRY)	Stry  Bankruptcy Court for the Western  STREET ADDRESS 3601 North I-27 TYPE ESTABLISHMENT INSPECTED		

and "R" approximately 1' east of "R";

g) Potential roof leak in northeast corner of north most room in the kitchen/old lab room; puddle of water observed on floor of room.

Paint chipping and peeling observed on ceiling over the dumping equipment located at northwest corner of the receiving/pre-clean area.

#### **OBSERVATION 5**

Failure to clean non-food-contact surfaces of equipment as frequently as necessary to protect against contamination.

Specifically,

On 2/9/09, at the following equipment non food-contact surface sites, an appreciable buildup of peanut fines, meal, chunks, or paste (some gooey other solidified) was observed:

- a) Drive chain upper sprocket of cup elevator for located directly over moving elevator cups (Processing Area);
- b) Drive chain sprocket of cup elevator in granulation room; site located next to moving elevator cups (Processing Area)
- c) Elevator in granulation room at southwest corner of granulation room; accumulation on northeast inside wall of sprocket directly next to moving elevator cups (Granulation Area);
- d) Drive chain sprocket of elevator located north of the blanching area beside the sorting machine; peanut debris on sprocket was directly over elevator cups (Processing Area).

Additionally, the Mode Vacuum-Packaging Machine was not cleaned both externally and internally as prescribed in the machine's operation manual. This piece of equipment was used to vacuum seal both repackaged product from the Blakely, GA facility and products manufactured at the Plainview, TX facility.

### **OBSERVATION 6**

Failure to dispose of adulterated food in a manner which protects against the contamination of other food.

Specifically,

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On 2/4/09, when conducting our initial walkthrough of the facility, various lots of recalled peanut product, specified as originating from the Blakely, GA plant, were palletized and placed among all other finished product lots designated as outgoing shipments. These products were not appropriately segregated, quarantined, or placarded as "on hold" or "defective". The potential for inadvertent shipment existed.

### **OBSERVATION 7**

Devices and fixtures are not designed and constructed to protect against recontamination of clean, sanitized hands.

Specifically,

The hot water foot-operated valve of the hand-washing sink at the primary entrance to the food processing area was not shutting off after use. To shut off the valve, the foot pedal had to be jiggled or pulled upward.

### **OBSERVATION 8**

There is no assurance that raw materials which are susceptible to contamination with aflatoxin or other natural toxins comply with current FDA standards before being incorporated into food.

Specifically,

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Upon review of records (aflatoxin COAs with incoming lot and/or laboratory peanut received logbook) specific to positive aflatoxin test results for the lots listed below, no records were found with the positive aflatoxin COAs to verify that the raw peanut lots initially testing positive for aflatoxin had been reconditioned and later tested and confirmed to be below FDA aflatoxin standards and action levels. These said lots of raw peanuts were processed into finished peanut products that were sold for human consumption.

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2043	10-20-08	1919	05-21-08	2009	09-04-08	
2061	11-12-08	1937	06-10-08	2008	09-04-08	
Peanut Lot #	Received	Peanut Lot #	Received	Peanut Lot #	Received	
PCA Raw	Date	PCA Raw	Date	PCA Raw	Date	

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

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2026	09-26 <b>-</b> 08	1892	04-	10-08	2011	09-06-08	
2006	09-04-08	1899	04-	25-08	1752	09-19-07	
1985	08-07-08	1877	04-	01-08	1753	09-20-07	
1967	07-18-08	1879	04-	02-08	1758	09-24-07	
1959	07-18-08	1880	04-	30-08	1733	09-11-07	
1961	07-09-08	1883	04-	04-08	1744	09-14-07	
1963	07-11-08	1874	03-	26-08	2013	09-10-08	
1944	06-18-08	1852	02-	29-08	2049	10-28-08	
1932	06-20-08	1826	01-	23-08	2005	09-03-08	
1949	06-26-08	1956	07-	02-08	2007	09-04-08	
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## \* DATES OF INSPECTION:

 $02/04/2009(Wed),\ 02/05/2009(Thu),\ 02/09/2009(Mon),\ 02/10/2009(Tue),\ 02/11/2009(Wed),\ 02/12/2009(Thu),\ 02/13/2009(Fri),\ 02/14/2009(Sat),\ 02/26/2009(Thu)$ 

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