

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 01/09/2009 - 02/05/2009*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Sammy L. Lightsey, Plant Operations Manager		FBI NUMBER 1036857
FIRM NAME Peanut Corporation Of America	STREET ADDRESS 14075 Magnolia St	
CITY, STATE, ZIP CODE, COUNTRY Blakely, GA 39823-1881	TYPE ESTABLISHMENT INSPECTED Peanut Roaster/Peanut Butter and Paste Manufacturer	
<p>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.</p>		
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, the firm's private laboratory microbiological testing found the following:		
<p>Salmonella Typhimurium: Peanut paste under lot # 8278 was found contaminated with Salmonella Typhimurium by private laboratory testing conducted by the firm. After the firm retested the product and received a negative status, the firm shipped (b)(4) of the product in interstate commerce. Additionally, this peanut paste was manufactured on 9/26/08 from (b)(4) lb. totes of roasted peanuts received on 9/25/08. The lots of roasted peanuts received on 9/25/08 were also used to produce the following products that were also shipped in interstate commerce: (b)(4) totes were used to manufacture (b)(4) peanut butter under lot # 8276; one tote was used to manufacture peanut butter for (b)(4) under lot # 8277 and (b)(4) (b)(4) under lot # 8277.</p>		
<p>Creamy Stabilized Peanut Butter, manufactured on 8/11/08 (producing both lots #8220 and #8224), tested positive for Salmonella by (b)(4) received the PCA sample for these lots on 8/12/08 and issued a report of positive results on 8/27/08. The isolate from this sample was sent to (b)(4) and was confirmed as Salmonella Anatum. The firm then had this lot retested at both (b)(4) and (b)(4) with both labs finding negative results. However, PCA had already shipped into interstate commerce the following: An 8/15/08 shipment of (b)(4) lbs. (invoice #0107013) creamy stabilized peanut butter under lot #8220 went to (b)(4)</p>		
<p>Lot #8268, Peanut Meal and Medium Chopped Peanuts, manufactured on 9/24/08, tested positive for Salmonella by (b)(4) (b)(4) received this PCA sample on 9/25/08 and issued a report of the positive results on 10/6/08. This sample was confirmed by (b)(4) as Salmonella Anatum. However, PCA had already shipped into interstate commerce the following lots before lab results were known: On 9/24/08 a shipment of (b)(4) lbs. (invoice #302583) of peanut meal under</p>		
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lot#8268 to (b)(4) On 9/25/08 a shipment of (b)(4) lbs. (invoice #1057536) medium chopped granules under lot #8268 went to (b)(4)		
Lot #8168, Medium Chopped Peanuts and Peanut Meal, manufactured on 6/16/08 tested positive for Salmonella by (b)(4) (b)(4) received the PCA sample for this lot on 6/17/08 and issued a report with the positive results on 6/23/08. The firm resubmitted a sample to (b)(4) on 6/21/08 with a report issued on 6/23/08 as negative. This firm had shipped the following product into interstate commerce prior to receiving the sample results on 6/23/08: A shipment on 6/18/08 of (b)(4) lbs. (invoice #662837) of peanut meal under lot #8169 went to (b)(4) On 6/20/08 this firm shipped approximately (b)(4) lbs. (invoice #61108) of peanut meal under lot #8169 to (b)(4)		
Lot #8161A, Small Chopped Peanuts, manufactured on 6/9/08, testing positive for Salmonella by (b)(4) (b)(4) received the PCA sample for this lot on 6/10/08 and issued a report with the positive results on 6/16/08. This firm resubmitted a sample to (b)(4) on 6/18/08 which was found to be negative per a report issued 6/21/08. PCA had already shipped product from lot# 8161A in interstate commerce before the positive results were known on 6/16/08. On 6/10/08 a shipment of approximately (b)(4) lbs. (invoice #MRB6408) of small chopped peanuts under lot #8161 went to (b)(4) On 6/13/08 a shipment of (b)(4) lbs. (invoice #11114-3) of small chopped peanuts under lot #8161 went to (b)(4)		
Lot #8028, Peanut Paste, manufactured on 1/25/08 tested positive for Salmonella by (b)(4) (b)(4) received the PCA sample for this lot on 1/26/08. However, also on 1/26/08 PCA shipped (b)(4) lbs. (invoice #4503605302) of peanut paste under lot #8028 to (b)(4)		
Salmonella (no strain identified): Medium Chopped Granules manufactured on January 24, 2008 under lot # 8024 tested positive for Salmonella by a private laboratory. After the firm retested the product and received a negative status, the product was shipped in interstate commerce.		
Lot # 7206, Small Chopped Peanut Granules, manufactured on or around 7/26/07, tested positive for Salmonella by (b)(4) (b)(4) received the PCA sample on 7/26/07 and issued a report of the positive results on 7/30/07. PCA had already shipped approximately (b)(4) lbs. (invoice #736434-001) of small chopped peanuts under lot #7206 to (b)(4) (b)(4) on 7/27/07 before the lab results were obtained.		
Lot #7192A, Small Chopped Peanuts, manufactured on 7/11/07, tested positive for Salmonella by (b)(4) (b)(4) received the PCA sample for this lot on 7/12/07 and issued a report of the positive Salmonella results on 7/18/07. Two more samples of this lot were submitted to both (b)(4) and (b)(4) The (b)(4) follow-up sample of this lot submitted on 7/18/07 was classified negative on 7/19/07. The (b)(4) follow-up sample of this lot		
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submitted on 7/18/07 was classified as positive for Salmonella. Records show that PCA shipped product from this lot prior to receiving the analytical results on 7/18/07. On 7/12/07 a shipment of approximately (b)(4) lbs. (invoice #LALIT70507) of small chopped peanuts under lot #7192 went to (b)(4). Also, on 7/12/07 a shipment of (b)(4) lbs. (invoice #732153-001) of small chopped peanuts under lot #7192 went to (b)(4).

Lot #7190B, Medium Chopped Peanuts, manufactured on 7/9/07, tested positive for Salmonella by (b)(4). (b)(4) received two PCA samples for lot #7190B on 7/10/07 and 7/12/07. Both samples were positive with the lab reports issued on 7/16/07 and 7/18/07 respectively. The following shipments were released into interstate commerce before the final lab results were obtained: On 7/11/07 a (b)(4) lb shipment of medium chopped peanuts (invoice #100986) under lot #7190 went to (b)(4). On 7/12/07 a (b)(4) lb shipment of medium chopped peanuts (invoice #18049-30) under lot #7190 went to (b)(4). On 7/13/07 a shipment of (b)(4) lbs of medium chopped peanuts (invoice #31810) under lot #7190 went to (b)(4) and on 7/13/07 a (b)(4) lb shipment of medium chopped peanuts (invoice #759) under lot #7190 went to (b)(4). Additionally, the firm made the following shipments on or after the positive Salmonella results were obtained: On 7/18/07 a shipment of (b)(4) lbs. of medium chopped peanuts (invoice #21479) under lot #7190 went to (b)(4) and on 7/24/07 a shipment of approximately (b)(4) lbs. of medium chopped peanuts (invoice #10872-2) under lot #7190 went to (b)(4).

Lot # 7190 B19-JR, Oil-Roasted Salted Jumbo Peanuts (b)(4) manufactured on 7/9/07 tested positive for Salmonella by (b)(4). (b)(4) received the PCA sample for this lot on 7/10/07 and issued a report of the positive results on 7/16/07. On 7/12/07 PCA submitted a second sample to (b)(4) of the same lot (#7190 B19-JR) and received a negative status for Salmonella on 7/16/07. The following shipments were released by PCA into interstate commerce before final lab results were known: A 7/10/07 shipment of (b)(4) lbs. (invoice #12131) oil roasted salted jumbo peanuts under lot #7190 went to (b)(4). A 7/12/07 shipment of (b)(4) lbs. (invoice #213157) oil roasted salted jumbo peanuts under lot #7190 went to (b)(4). A 7/12/07 shipment of approximately (b)(4) lbs. (invoice #213158) oil roasted salted jumbo peanuts under lot #7190 went to (b)(4). A 7/13/07 shipment of approximately (b)(4) lbs. (invoice #11463) oil roasted salted jumbo peanuts under lot #7190 went to (b)(4).

Lot # 7157, Small Chopped Peanut Granules, manufactured on 6/7/07, tested positive for Salmonella by (b)(4). (b)(4) received the PCA sample on 6/7/07 and issued a report of the positive results on 6/13/07. However, PCA had already shipped (b)(4) lbs (invoice # 721676-001) of small chopped peanuts under lot #7157 to (b)(4) (b)(4) on 6/7/07 before the lab results were obtained.

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OBSERVATION 2		
Failure to maintain equipment, containers and utensils used to convey, hold, and store food in a manner that protects against contamination.		
Specifically, the peanut paste line was not cleaned after the Salmonella Typhimurium was isolated from the peanut paste manufactured on September 26, 2008 (lot # 8278). The firm continued to manufacture peanut paste in this system from 9/26/08 to the beginning of this inspection on 1/9/09. (b)(4) lots of peanut paste have been manufactured on this line between 9/26/08 and 1/9/09.		
There are no records to document the cleaning of the peanut paste line after Salmonella was detected in peanut paste manufactured on January 25, 2008 (lot # 8028). The firm continued to manufacture peanut paste in this system.		
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OBSERVATION 3		
Failure to perform mechanical manufacturing steps so as to protect food against contamination.		
Specifically, this firm recognizes the roasting step as the control point for eliminating microbiological contamination in raw materials. However, this firm has not established the effectiveness of the temperature, volume, or belt speed specific to this roaster to assure it is adequate as a kill step for pathogenic bacteria. Additionally, the firm's records of the roaster's temperature are inadequate in that dates have been left off of several circular recording charts. For example, in August 2008 three days of recording charts were not dated; in September 2008 two recording charts were not dated; in October 2008 six charts were not dated; in November 2008 24 days of recording charts were not dated; and in December 2008 and January 2009 no temperature recording charts were dated.		
OBSERVATION 4		
Failure to store finished food under conditions that would protect against microbial contamination.		
Specifically, on 1/9/09 (b)(4) lb. totes of raw peanuts were observed to be stored directly next to (b)(4) lb. totes of finished, roasted peanuts in the firm's production/packaging room. The totes of finished product included the following: Honey Roasted Peanuts under lot # 8339; Dry Roasted Peanuts under lot # 9002; Peanut Meal under lot # 9005; and Dark Roasted Peanuts (paste line) under lot # 9009. The (b)(4) totes of raw peanuts were all under lot # 40147. On 1/26/09, an additional (b)(4) lb. tote of raw peanuts under lot # 16195-08 was observed to be stored in the production/packaging room along with the same lots of finished goods listed above. It was visually difficult to discern which of these totes were finished products and which were raw products.		
The above totes of finished product were stored within 15 feet of a floor crack where an environmental swab was collected on 1/10/09 and found positive for Salmonella Senftenberg.		
Also, one environmental swab collected on 1/10/09 from the finished product cooler floor (beside the south wall) was found positive for Salmonella Mbandaka. The swab location was within 3 feet of pallets of finished product.		
Mold was observed growing on the ceiling and walls in the firm's cooler used for finished product storage. In addition, water stains were observed running down from the cooling unit fans in the cooler. On 1/10/09, pallets of finished product were stored directly beneath this unit.		
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OBSERVATION 5		
<p>The plant is not constructed in such a manner as to allow ceilings to be kept in good repair.</p> <p>Specifically, on 1/10/09 there were open gaps observed as large as 1/2" x 2 1/2 feet at the air conditioner intakes located in the roof of the firm. Water stains were also observed on the ceiling around the air conditioner intakes. Additionally, there were water stains and streaks located on the edges of the skylights where rain water has been leaking into the firm. All of these openings were located in the production/packaging room. Totes of finished, roasted product and a roasted nut packaging line are located directly underneath these areas.</p>		
OBSERVATION 6		
<p>The design of equipment and utensils fails to preclude the adulteration of food with contaminants.</p> <p>Specifically, a felt material is present on the final roller at the roaster's discharge. This material cannot be adequately cleaned or sanitized.</p> <p>Also, the rework kettle in the peanut butter room had openings (2" x 3") at the top exposing the peanut butter to open conditions.</p>		
OBSERVATION 7		
<p>Proper precautions to protect food and food-contact surfaces from contamination with microorganisms cannot be taken because of deficiencies in plant construction and design.</p> <p>Specifically, the firm is not equipped with a ventilation system to prevent cross-contamination by providing a negative room pressure in the facility. A negative room pressure would direct air flow from the finished product areas into the negative pressure room (raw peanut receipt and staging area), ensuring that contaminated air does not escape to other parts of the facility.</p> <p>The raw peanut receipt/staging area, peanut paste tanker line, peanut roasters, and the peanut granule line are housed in the same open room with no segregation. In addition, the honey roasted peanuts, considered to be finished product, are filled into</p>		
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<p>boxes utilizing a hopper in the "kitchen area", this location is where the raw peanuts enter the roaster, again no segregation. Raw peanuts are filled into boxes utilizing a hopper located in the Production/Packaging room. This hopper is positioned above the packaging line for the small party packs of roasted peanuts. There is no segregation of raw and finished product in this area.</p>		
OBSERVATION 8		
<p>Devices and fixtures are not designed and constructed to protect against recontamination of clean, sanitized hands.</p> <p>Specifically, the sink located in the peanut butter room is used interchangeably as a point for cleaning hands and utensils and for washing out mops.</p>		
OBSERVATION 9		
<p>Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food.</p> <p>Specifically, on 1/12/09 a build-up of product residue was observed on grinders, hoppers, and support beams on the peanut paste tanker line. Also, pieces of the yellow and black caution sign on the (b)(4) mill were flaking off into the catch pan for product under the mill.</p> <p>On 1/9/09, the dry ingredient staging area above the peanut butter room was dirty with a heavy build-up of different powdery ingredients on all exposed surfaces. This is an open area of the ceiling located directly above the dry ingredient hopper and ribbon mixer.</p> <p>On 1/9/09, a mesh-type conveyor was observed to be stored in the firm's equipment/utensil wash room, which was used as a catch-all storage area for buckets, stainless steel pipes, removable pumps, removable Y-spouts, and floor mats. The insides and end rollers of this conveyor were covered with a slimy, black-brown residue. Additionally, the bottom sections of the wash room walls had areas of mold.</p>		
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OBSERVATION 10		
Effective measures are not being taken to protect against the contamination of food on the premises by pests.		
Specifically, on 1/9/09 a live roach and several dead roaches were observed in the firm's wash room. This wash room is adjacent to the production/packaging area.		
Also, the bumper pads used for sealing the trailers against the bay doors were inadequate in that openings of 6 inches or more were observed along the sides and tops of the trailers. These trailers, containing raw or roasted product in totes, can be left backed up to the bay doors for 5-7 days allowing these openings to exist.		
* DATES OF INSPECTION: 01/09/2009(Fri), 01/12/2009(Mon), 01/13/2009(Tue), 01/14/2009(Wed), 01/15/2009(Thu), 01/16/2009(Fri), 01/19/2009(Mon), 01/20/2009(Tue), 01/21/2009(Wed), 01/22/2009(Thu), 01/23/2009(Fri), 01/26/2009(Mon), 01/27/2009(Tue), 02/05/2009(Thu)		
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