

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 - 01/27/2009*
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>		
<p>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</p>		
<p>OBSERVATION 1</p>		
<p>Failure to manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.</p>		
<p>Specifically, the firm's own internal microbiological testing found the following:</p>		
<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) lb. 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) under lot # 8277.</p>		
<p>Salmonella Anatum: Peanut Butter manufactured on 8/11/08 under lot # 8220 and # 8224 tested positive for Salmonella Anatum by a private laboratory. After the firm retested the product and received a negative status, the product was shipped in interstate commerce.</p>		
<p>Salmonella Anatum: Peanut Meal and Medium Chopped Granules manufactured on September 24, 2008 under lot # 8268 tested positive for Salmonella Anatum by a private laboratory. After the firm retested the product and received a negative status, the product was shipped in interstate commerce.</p>		
<p>Salmonella (no strain identified): Medium Chopped Granules manufactured on June 16, 2008 under lot # 8168 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.</p>		
<p>Salmonella (no strain identified): Small Chopped Granules manufactured on June 9, 2008 under lot # 8161 tested positive for Salmonella by a private laboratory. After the firm retested the product and received a negative status, the product was shipped</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Janet B Gray, Investigator <i>JBG</i> Darcy E. Brillhart, Microbiologist Sandra I. Gaul, Investigator Robert P. Neligan, Investigator <i>RPN</i> Lesley K. Satterwhite, Microbiologist Theresa L. Stewart, Investigator <i>TLS</i>	01/27/2009
FORM FDA 483 (04/03)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS
		PAGE 1 OF 6 PAGES

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 - 01/27/2009*
		FBI NUMBER 1036857
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Sammy L. Lightsey, Plant Operations Manager		
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>in interstate commerce.</p> <p>Salmonella (no strain identified): Peanut Paste manufactured on January 25, 2008 under lot # 8028 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.</p> <p>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.</p> <p>Salmonella (no strain identified): Small Peanut Granules manufactured in July of 2007 under lot # 7206 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.</p> <p>Salmonella (no strain identified): Small Peanut Granules manufactured in July of 2007 under lot # 7192A 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.</p> <p>Salmonella (no strain identified): Medium Peanut Granules manufactured in July of 2007 under lot # 7190B 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.</p> <p>Salmonella (no strain identified): Oil-Roasted Salted Peanuts (b)(4) manufactured in July of 2007 under lot # 7190-B19-JR 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.</p> <p>Salmonella (no strain identified): Small Peanut Granules manufactured in June of 2007 under lot # 7157 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.</p>		
OBSERVATION 2		
<p>Failure to maintain equipment, containers and utensils used to convey, hold, and store food in a manner that protects against contamination.</p> <p>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.</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Janet B Gray, Investigator <i>JBG</i> Darcy E. Brillhart, Microbiologist Sandra I. Gaul, Investigator Robert P. Nelligan, Investigator <i>RPN</i> Lesley K. Satterwhite, Microbiologist Theresa L. Stewart, Investigator <i>TLS</i>	01/27/2009
FORM FDA 482 (04/03)	PREVIOUS EDITION OBSOLETE	PAGE 2 OF 6 PAGES

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 - 01/27/2009* FET NUMBER 1036857
--	--

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Sammy L. Lightsey, Plant Operations Manager

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

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.

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)} 2000 lb. totes of raw peanuts were observed to be stored directly next to 2000 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 2000 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.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Janet B Gray, Investigator <i>JBG</i> Darcy E. Brillhart, Microbiologist Sandra I. Gaul, Investigator Robert P. Neligan, Investigator <i>RPN</i> Lesley K. Satterwhite, Microbiologist Theresa L. Stewart, Investigator <i>TLS</i>	DATE ISSUED 01/27/2009
--------------------------	--	---------------------------

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 - 01/27/2009* PEI NUMBER 1036857		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Sammy L. Lightsey, Plant Operations Manager			
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		
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>			
SEE REVERSE OF THIS PAGE	<table border="1"> <tr> <td>EMPLOYEE(S) SIGNATURE Janet B Gray, Investigator <i>JBG</i> Darcy E. Brillhart, Microbiologist Sandra I. Gaul, Investigator Robert P. Neligan, Investigator <i>RPN</i> Lesley K. Satterwhite, Microbiologist Theresa L. Stewart, Investigator <i>pls</i></td> <td>DATE ISSUED 01/27/2009</td> </tr> </table>	EMPLOYEE(S) SIGNATURE Janet B Gray, Investigator <i>JBG</i> Darcy E. Brillhart, Microbiologist Sandra I. Gaul, Investigator Robert P. Neligan, Investigator <i>RPN</i> Lesley K. Satterwhite, Microbiologist Theresa L. Stewart, Investigator <i>pls</i>	DATE ISSUED 01/27/2009
EMPLOYEE(S) SIGNATURE Janet B Gray, Investigator <i>JBG</i> Darcy E. Brillhart, Microbiologist Sandra I. Gaul, Investigator Robert P. Neligan, Investigator <i>RPN</i> Lesley K. Satterwhite, Microbiologist Theresa L. Stewart, Investigator <i>pls</i>	DATE ISSUED 01/27/2009		

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 - 01/27/2009*
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>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>		
<p>OBSERVATION 8</p> <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>		
<p>OBSERVATION 9</p> <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>		
<p>OBSERVATION 10</p> <p>Effective measures are not being taken to protect against the contamination of food on the premises by pests.</p> <p>Specifically, on 1/9/09 a live roach and several dead roaches were observed in the firm's wash room. This wash room is</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Janet B Gray, Investigator Darcy E. Brillhart, Microbiologist Sandra I. Gaul, Investigator Robert P. Neligan, Investigator Lesley K. Satterwhite, Microbiologist Theresa L. Stewart, Investigator	DATE ISSUED 01/27/2009

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 - 01/27/2009* FEI NUMBER 1036857
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Sammy L. Lightsey, Plant Operations Manager		
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>adjacent to the production/packaging area.</p> <p>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.</p>		
<p>* DATES OF INSPECTION: 01/09/2009(Fri), 01/10/2009(Sat), 01/11/2009(Sun), 01/12/2009(Mon), 01/13/2009(Tue), 01/14/2009(Wed), 01/15/2009(Thu), 01/16/2009(Fri), 01/20/2009(Tue), 01/23/2009(Fri), 01/24/2009(Sat), 01/25/2009(Sun), 01/26/2009(Mon), 01/27/2009(Tue)</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Janet B Gray, Investigator Darcy E. Brillhart, Microbiologist Sandra I. Gaul, Investigator Robert P. Neligan, Investigator Lesley K. Satterwhite, Microbiologist Theresa L. Stewart, Investigator	DATE ISSUED 01/27/2009