

**Establishment Inspection Report**ConAgra Grocery Products  
Sylvester, GA 31791-0585

FEI: 1038538

EI Start: 02/14/2007

EI End: 03/02/2007

**SUMMARY**

The current inspection of this peanut butter manufacturer was conducted as per a directed assignment from ATL-DO to conduct an inspection of this firm prompted by the notification from FDA's Office of Emergency Operations of a suspected food-borne illness outbreak of *Salmonella Tennessee*. Extensive epidemiological testing and case control studies collected by the CDC identified peanut butter manufactured by ConAgra Grocery Products in Sylvester, GA as the likely source of the ongoing outbreak. According to the CDC data, this is a multi-state outbreak with onset dates ranging from August 1, 2006 to January 21, 2007. See ATTACHMENT A for detailed background information for this outbreak.

Investigators were instructed to start the follow-up inspection of ConAgra Foods in Sylvester, GA as soon as possible on 2/14/07. Based on case control studies by the CDC, lot codes from containers of peanut butter found in the homes of patient's with confirmed *Salmonella Tennessee* were provided to FDA. Instructions issued to the FDA Investigators included collecting environmental swabs throughout the plant, collecting finished product and raw ingredient samples, reviewing records pertaining to quality control and production (initially concentrating on suspect lot code dates provided and the onset time frame of the outbreak).

This firm operates as the only manufacturer of Peter Pan Peanut Butter Products and one of several producers of (b)(4) Peanut Butter products (b)(4) brand). The focus of the current inspection was to determine if and what products manufactured at this firm were contaminated with *Salmonella* and any possible sources of product contamination in the firm. At 6:30 p.m. on 2/14/07, the firm voluntarily shut down operations; therefore, the inspection of the firm's equipment and production lines in operation was limited. Other areas covered during the inspection included in-house testing results and procedures, consumer complaints, maintenance and installation of equipment, cleaning and sanitizing procedures, raw materials/ingredients, product inventory and distribution, record review, and sample collections. Numerous samples, consisting of finished product, raw ingredients, and environmental swabs, were collected during the inspection, and shipped to the Southeast Regional Lab for *Salmonella* analysis. DOC sample #409799 was collected to document the interstate commerce of (b)(4) cases of Peter Pan Products shipped from ConAgra Grocery Products, Sylvester, GA to (b)(4) on 2/14/07. Descriptions of samples collected are included in the "Samples Collected" section at the end of this report. Collection Reports for these samples are attached to the report.

**ADMINISTRATIVE DATA**

Inspected firm: ConAgra Grocery Products  
Location: 101 S Seabrook Dr  
P.O. Box 585  
Sylvester, GA 31791-0585  
Phone: 229-776-8811

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**FAX:**

Mailing address: 101 S Seabrook Dr/P.B. 585  
Sylvester, GA 31791

Dates of inspection: 2/14/2007, 2/15/2007, 2/16/2007, 2/17/2007, 2/18/2007, 2/19/2007,  
2/20/2007, 2/21/2007, 2/22/2007, 2/23/2007, 2/26/2007, 2/27/2007,  
2/28/2007, 3/1/2007, 3/2/2007

Days in the facility: 15

Participants: Janet B Gray, Investigator  
Jackie M. Douglas, Investigator

**HISTORY**

This firm operates as a division of ConAgra Foods, Inc. under the Canning Platform. The corporate office for ConAgra is located at 1 ConAgra Drive, Omaha, NE 68102 and the home office for the Canning Platform is located in Naperville, IL. The division office is located in Irvine, CA. Mr. Gary Rodkin was identified as the CEO of ConAgra Foods, Omaha, NE. See EXHIBIT # 1 for the organizational chart for ConAgra Foods. Mr. Gary Rodkin is the CEO and most responsible individual for ConAgra Foods Inc. Individuals responsible for operations and QA at this location were identified as Earl G. Ehret, Plant Manager, and A. Joseph (Joey) Kimbrell, Quality Control Manager. Numerous members of management from this location and other divisions were present during the inspection. Each name and title of everyone involved are listed under the "Persons Interviewed and Individual Responsibility" heading of this report.

The previous inspection of this firm on 2/23-24/05 was conducted in response to several consumer complaints including an anonymous complaint with specific allegations of an episode of positive findings of *Salmonella* in peanut butter in October of 2004. The complainant also alleged that the firm had an insufficient response to the microbial problems relating to inadequate cleaning of new equipment, insect activity in plant, water leaking onto product, and inability to track some product. Management verbally reported that (b)(4) production is tested in-house for *Salmonella* and (b)(4) prior to the release of the product. The firm acknowledged that there was some production in October of 2004 that did not meet product specifications and was put on a "Micro" hold, and was subsequently destroyed. Management refused to provide details to include the exact cause of the hold and the type/amount of product involved. The firm did provide a review of micro testing results on 2 dates in October that were reported to be 2 dates on which new votators (heat exchangers) were placed on the lines after having been cleaned and sanitized. Tests on both dates were "negative" for *Salmonella* and coliforms.

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The previous inspection revealed areas of (b)(4) packaging lines where filled containers of peanut butter were not completely covered, and both were corrected during the inspection. The Investigator did not find any leaking water lines or overhead condensation, etc. leaking into any exposed product, either on packaging lines or in the raw and roasted peanut handling areas. No evidence of insects or activity were observed around the product elevators and elevator boots, bins, aspiration lines, foreign material chutes, destoners, blanchers, or electronic sorters. Management expressed concern over the complaints and reported that some of the allegations are time-related to (b)(4) and that recent plant mechanization resulting in a number of employees losing their jobs has resulted in some employee resentment. A FDA 483, Inspectional Observations, was not issued, but several concerns were verbally discussed with management. A finished product sample of peanut butter produced during the inspection on 2/24/05 was collected and submitted to SRL for microbial analysis. Lab analysis revealed that the sample was negative. The firm has no regulatory history.

Approximately 1 hour into the current inspection, Robert Rish, District Supervisor and Bill Jones, Sanitarian/Inspector with the Georgia Department of Agriculture requested a joint inspection of the plant. The request was granted and GDA inspectors joined the inspection. Mr. Rish was present during the inspection from 2/14-21/07. Inspector Jones accompanied the Investigators every day of the inspection, except for the closing on 3/2/07. The GDA collected finished product samples in conjunction with the FDA Investigators.

**INTERSTATE COMMERCE**

The firm's finished products are routinely shipped to various distribution centers located throughout the country, see EXHIBIT # 2 for a copy of the distribution/inventory centers used by the firm. Additionally, the firm ships some product directly (b)(4) stores. See EXHIBIT # 3 for the product inventory by location as of 2/17/07 for products shipped from this plant. EXHIBIT # 4 is a list of the product codes or SKU numbers used by the firm to identify product types and sizes.

**Documentary Sample # 409799** documents the interstate commerce of (b)(4) cases of Peter Pan Products shipped from ConAgra Grocery Products, Sylvester, GA to (b)(4) (b)(4) on 2/14/07. The Collection Report, attached to this report, includes the FDA-463a, Affidavit, read and signed by the Plant Manager, and the Bill of Lading for the above shipment.

**Sample # 409792**, collected on 2/21/07 consisted of 15/18 oz. jars of (b)(4) Peanut Butter Spread collected from the firm's warehouse inventory. Included with the collection report is Shipping Ticket, PPSID # 39270, dated 2/6/07, from (b)(4) in (b)(4) (b)(4) to ConAgra Grocery Products in Sylvester, GA documenting the IS movement of (b)(4) kg. boxes of (b)(4) lot # 10701123, used as an ingredient in the manufacture of (b)(4) Peanut Butter Spread. The FDA-463a also documents the use of this ingredient in the firm's operations and the IS of this ingredient.

The collection report and corresponding records for the above samples are attached to this report.

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**JURISDICTION**

The firm manufactures a variety of peanut butter products packaged under the Peter Pan label and (b)(4) label, which include the following:

Peter Pan Creamy (18, 22, 28, 40, and 56 oz., 6 lb, 500 lb.)

Peter Pan Crunchy (18, 22, 28, and 40 oz.)

Peter Pan Creamy Honey Roast Peanut Butter (18 and 28 oz.)

Peter Pan Crunchy Honey Roast Peanut Butter (18 oz.)

Peter Pan Creamy No Sugar Added Peanut Spread (18 oz.)

Peter Pan Creamy Whipped Peanut Butter (14 oz.)

Peter Pan Creamy Plus Peanut Butter with Vitamins and Minerals (17.6 oz.)

Peter Pan Creamy Reduced Fat Peanut Butter Spread (18 and 28 oz.)

Peter Pan Crunchy Reduced Fat Peanut Butter Spread (18 oz.)

(b)(4) Creamy Peanut Butter (18, 28, and 40 oz.)

(b)(4) Crunchy Peanut Butter (18, 28 and 40 oz.)

(b)(4) Reduce Fat Peanut Butter Spread (18 oz.)

See EXHIBIT # 5 for the product labels provided by the firm. [Note: the firm no longer packages peanut butter in 12 oz. containers (label on page 1 of Exhibit # 5), and no products have been produced under the (b)(4) label since 2002 (label on page 5 of Exhibit # 5); however, these labels were also provided.]

The majority of the peanut butter products are packaged in plastic jars with plastic screw cap lids. The 6 lb. containers of peanut butter are packaged in foil lined cardboard composite barrels, with metal lids. The label for this product is included with EXHIBIT # 5. The bulk peanut butter is packaged in 55 gallon cardboard fiber drums with a plastic interior lining with a metal sealing ring, see EXHIBIT # 6 for a copy of a drum label and EXHIBIT # 7 for the Letter of Inspection from the drum supplier. The bulk drums of peanut butter are shipped internally to two locations: ConAgra portion pack plant located in (b)(4) packaged under the Peter Pan label; and the ConAgra (b)(4) plant distributing ice cream topping under the (b)(4) label.

According to the firm, peanut butter products produced at this plant are only packaged under Peter Pan and (b)(4) labels. (b)(4) butters are produced at this firm. The firm indicated that approximately 6-7 years ago they had produced peanut butter under the private label (b)(4). When they stopped producing this product (b)(4) (peanut butter manufacturer located in (b)(4)) took over the production of this product. Also, at one time the firm had packaged peanut butter for small "mom and pop" type stores, under (b)(4) label (this was so far back that no one at the firm knew exactly how long ago this was). Management informed us that at this time, no other labels are used by this firm and the Peter Pan jar shapes are proprietary.

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According to the firm, only domestic peanuts, primarily from (b)(4) are used in the production of their peanut butter products (i.e. (b)(4))

The firm normally receives raw peanuts in bulk tanker trucks, but occasionally the firm receives raw peanuts in (b)(4) capacity bulk cardboard boxes or totes from (b)(4) facilities, such as (b)(4). Each lot of raw peanuts is accompanied with a USDA certificate of analysis (COA), which is reviewed prior to releasing the peanuts for processing.

Additional raw ingredients used for the manufacture of peanut butter products at this plant include

(b)(4)  
Photographed labels of raw ingredients on hand at the plant were provided by the firm (EXHIBIT # 8). The firm (b)(4) incoming raw materials except for (b)(4) which are checked for (b)(4). (b)(4) Ingredients are purchased from approved suppliers and each lot comes with a COA. Microbial specifications are included on the COA's provided with the (b)(4) and (b)(4) see EXHIBIT # 9.

Packaging supplies used by the firm include caps, jars, trays, cans, labels, etc. The source and list of raw ingredients and materials used for the firm's manufacturing operations is included as EXHIBIT # 10. Materials are visually examined upon receipt for damage and defects. As jars come into the warehouse, they are checked for foreign material, correct size, moisture, damage and defects. The firm does not receive a COA or conduct lab testing on jars and caps. The investigator's inquired if they had experienced any problems or had any recalls with their ingredients or packaging materials within the last year. Management said that the only problems they had concerned some defected jars that were rejected upon receipt and a few pallets of jars that were rejected because some evidence of moisture was detected. The Quality Control Manager provided us with the Shipping Ticket and Hold notice for the shipment of 2 pallets of "wet" jars shipped to the firm on March of 2006. The jars were rejected and returned to the supplier, see EXHIBIT # 11. Additionally, management stated that approximately 2 years ago the firm had received a lot of raw peanuts that "failed" the (b)(4). The lot was delivered to the firm and unloaded into the storage bins, but they were notified of the (b)(4) analysis before the lot was used. Reportedly, Federal and State officials were notified of the incident. According to management, the firm has not received any recalls from their suppliers for the past 2 years.

Oil or lubricants are used on various equipment throughout the process flow. See EXIHIBIT # 12 for a list of the lubricants, venders, and where used. There is no water added as an ingredient for the products manufactured at this plant. The firm has city water and it is used only for clean out of place (COP) equipment and mopping floors.

**PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITY**

The inspection was initiated on 2/14/07. Credentials were presented to and the FDA-482, Notice of Inspection, (and "Resources for FDA Regulated Businesses" document) was issued to Mr. Earl G. Ehret, Plant Manager. Present also at this time were the following members of management: Chris

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C. Horan, Director of Enterprise Quality; A. Joseph (Joey) Kimbrell, Quality Control Manager; Erdal Tuncan, Director of Microbiology; and Tom Cherven, Enterprise Sanitation Manager.

FDA correspondence should be sent to Don Jones, Sr. Director of Quality and Food Safety, Omaha, NE. The corporate office gave the final authorization allowing us to review or receive a copy of records requested during the inspection. Delays experienced during the inspection concerning access to records were due to the fact that the firm was required to make a copy of each record provided to the FDA and all of these records had to be passed through the corporate office before being released to the Investigators. Also, some information requested by the FDA was not part of the firm's standard procedures or records, and had to be compiled by various members of management.

Ms. Chris C. Horan, Director of Enterprise Quality, stated that she works in the Irvine, CA office, and she reports to Don Jones in the corporate office in Omaha, NE. She reported that she is the Quality Director over the canning and grocery division of ConAgra. During the inspection, Ms. Horan acted as the liaison between the Sylvester plant and the corporate office. She was responsible for sending all record requests through the corporate office for permission to provide documents to the Investigators. Ms. Horan was present for each discussion during the inspection, except for the closing on 3/2/07. She provided intermittent accompaniment during sample collections and plant walk-through. The majority of the records given to FDA were provided by Ms. Horan.

Mr. Earl G. Ehret is the Plant Manager of this facility and the most responsible individual for the day-to-day operations at this facility. Shortly after the arrival at the firm, we were informed that Mr. Ehret has been the Plant Manger for only 3 weeks. He said that his official start date at the firm was 1/15/07, and he had replaced Mr. (b)(4) the previous Plant Manager. Mr. Ehret told us that he would cooperate in any way that he could, but information concerning specific details of the operation and events that occurred prior to his arrival would be difficult for him to answer. Mr. Ehret provided accompaniment throughout the inspection. The FDA-482, Notice of Inspection, and FDA-484, Receipt for Samples, was issued to Mr. Ehret. In addition, he read and signed the FDA 463a, Affidavit, during the closing discussion.

Mr. A. Joseph Kimbrell, Quality Control Manager, is responsible for all quality control functions in the plant, including, cleaning and sanitation procedures and in-house tests for finished product and environmental swabs. Mr. Kimbrell provided accompaniment throughout the inspection. Mr. Kimbrell provided information pertaining to laboratory procedures, cleaning supplies, sanitation program, and methodology for in-house tests.

Thomas Gentle, former Plant Manager, joined the inspection on 2/15/07. Mr. Gentle now works in the Omaha, NE office, but he stated that the corporate office ask that he come down to the Sylvester plant to assist in the walk-through inspection of the plant since he was familiar with the equipment and operations. During the initial walk-through of the production area, Mr. Gentle described the equipment and process flow of the plant. He accompanied us each day of the inspection until his

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departure on 2/20/07.

Erdal Tuncan, Director of Microbiology, Omaha, NE, provided information pertaining to in-house testing procedures, and he collected environmental swabs for the firm on 2/15/07. Mr. Tuncan was present for the inspection from 2/14-2/16/07.

LaLit Boltra, Senior Microbiologist, Omaha, NE, provided intermittent accompaniment during the inspection, and he reports to Mr. Tuncan.

Tom Cherven, Sanitation Manager Enterprise Quality, Naperville, IL, provided intermittent accompaniment during the inspection and information for sanitation policies.

Other key operations personnel at the Sylvester, GA plant included:

Dennis Yeckel, Production Manager, provided accompaniment during sample collections, and supplied information pertaining to production lines and product inventory.

Joe Malinowski, Production Supervisor, accompanied us during walk-through inspections of the plant. He provided information pertaining to the process flow, equipment functions (i.e. roaster, homogenizer, votators, and diaphragm valves).

Dave Taylor, Maintenance Supervisor, provided information pertaining to maintenance and repairs of equipment in plant, such as maintenance of closed system (Line Entry Permit) and additives for cooling towers.

Clarence Davis, 2nd Shift Production Supervisor, Chuck Hobby, Focused Improvement, and Matt Jordan, Maintenance Supervisor, accompanied us during the collection of environmental swabs and finished product sampling, and provided information pertaining to production lines, and equipment functions.

Tabitha Giddens, Cost Manager, provided assistance in record requests and provided information pertaining to the history of firm.

At the initiation of the inspection, we explained that the inspection was in response to the CDC's epidemiological findings implicating peanut butter manufactured from this firm as the source of a food borne outbreak linked to *Salmonella Tennessee*. We discussed that CDC's data covered a time period of August 2006 to December of 2006. Management told us that they were already aware of the implications, but they had just found out the previous night and they did not have any idea of the products or production dates involved. Ms. Horan stated that they had been busy reviewing records from January 2006 to the present, and they had not found any indications of problems. She commented that their ingredient suppliers had not issued any product recalls. We explained that there did not appear to be one specific product or a specific production date implicated. We told

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them that we had a list provided by the CDC that identified certain products and the lot codes gathered from the open jars found in the homes of the consumers involved in the outbreak. We explained that we were given permission to share the lot codes with the firm, but any other questions concerning statistics or studies involving the outbreak should be discussed with the CDC. We reminded them to keep in mind that the codes were not all complete and might not follow their coding system exactly due to the fact that the codes were gathered by the consumers and/or state employees across the United States. The following products and lot codes are quoted directly from CDC's cluster study list provided to FDA. Note that some codes appear to be missing #'s (i.e. "211"); however, the codes were listed as such and provided to the firm as follows:

<u>Product</u>	<u>Lot Code</u>	<u>Use By Date</u>
Peter Pan Creamy	211163460014020	6122008
Peter Pan Creamy	211162430008340	08/2012
Peter Pan Creamy	21116248000543 B	03052008
Peter Pan Creamy	21115251000805A	03082008
Peter Pan Creamy	211427300223913	3302006
Peter Pan Creamy	211163380021598	06042008
Peter Pan Creamy	21116258002929A	312008
Peter Pan Crunchy	21116094000807A	1042007
Peter Pan Honey Roast	21162360013098	02242008
Peter Pan	211111???7002249	2252008
Peter Pan Creamy Smart Choice	211163260022480	5222008
(b)(4) Crunchy	2111634100210A	672008
(b)(4) Crunchy	2116213000022C	02012008

From this information, Mr. Kimbrell was able to trace the production date for the suspect products, EXHIBIT # 13. We ask to review the finished product test results for these specific dates, and Ms. Horan stated that she would find out through the corporate headquarters if it would be okay for us to review the records. After some time, Ms. Horan allowed us to review the finished product test results for the suspect lots. No deficiencies were found during the review. Copies of these records were subsequently provided to the Investigators and included as EXHIBIT # 14.

The Investigators told the firm that this inspection would more than likely be extensive and that our immediate instructions were to collect environmental swabs throughout the plant. We explained that 2 microbiologist from the Southeast Regional Lab would be joining us on the following day to assist with the collection of the environmental swabs.

We told the firm that we would like to collect finished product samples, and we ask if there was a chance that they still had product in their warehouse that was produced within the same time frame as some of the suspect production dates. We were informed that they usually don't have anything



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older than (b)(4) weeks in the warehouse, but they would check their inventory. After checking the inventory we were told that the oldest product they had was 18 oz. Peter Pan Creamy produced on (b)(4). We attempted to find product produced on or around the suspect production dates, therefore, 3 of the oldest dated products were collected on 2/14/07 from the firm's warehouse inventory.

Sample # 366079 consisting of 15/18 oz. jars of Peter Pan Creamy Peanut Butter, production date 12/07/06, were collected from the sampled lot of (b)(4) cases in the firm's warehouse. This product was produced for export, thus the lot code varied from the usual coding system. Each jar had a code printed in dot-matrix on the top of the lid of "PRD 11/09/06" "EXP 11/09/0 (b)(4)".  
Sample # 366080 consisting of 15/18 oz. jars of (b)(4) Crunchy Peanut Butter, production date 12/7/06, were collected from the sample lot of (b)(4) cases in the firm's warehouse. Sample # 366076 consisting of 15/22 oz. jars of Peter Pan Crunchy Peanut Butter, production date 11/16/06, were collected from the sampled lot of (b)(4) cases in the firm's warehouse. The Collection Reports for the above samples are attached to this report. FDA-484 for the above samples was issued to Mr. Earl Ehret, Plant Manger, at the end of the day on 2/14/07.

**OPERATIONS, PERSONNEL, AND EQUIPMENT**

**[INFORMATION IN THIS SECTION IS PROPRIETARY AND CONSIDERED A TRADE SECRET BY THE FIRM.]**

The firm is currently operating (b)(4) days per week, running (b)(4) hour shifts per day. The (b)(4) shift runs from (b)(4) M, and the (b)(4) shift from (b)(4) Ms. Horan said that they had been operating with (b)(4) shifts for the past (b)(4) years, but approximately 2 weeks ago they changed and went (b)(4) shifts. Sanitation operations are staffed 24 hours per day, with any major clean-ups performed during the down time from (b)(4) and on weekends. The firm has (b)(4) hourly and (b)(4) salaried employees.

**Processing Flow/Equipment**

[It should be noted that after the Investigators left the firm on 2/14/07, first day of inspection, the firm voluntarily shut down operations around 6:30 p.m. The first day of the inspection was spent interviewing management, discussing and requesting records, and collecting 3 finished product samples. Thus, we did not observe the production of peanut butter during the inspection.]

The manufacturing process since the last FDA inspection in February of 2005 has not changed. The production equipment and operations found at this firm are typical to the industry. See EXHIBIT # 22 for plant diagrams of the firm.

Raw peanuts are shipped to the firm in dedicated bulk tankers owned by (b)(4). The raw peanuts are vacuumed out of the tankers and off-loaded into bulk bins for temporary holding. The bulk bins are split into (b)(4) mounting to (b)(4) separate bins, each with the capacity of (b)(4) (b)(4) lbs. Each bulk bin has a ticket on the side identifying the bin #, lot # of raw peanuts (first 2

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#'s of lot identify the supplier), date the lot was received, and the # of bulk delivery truck. The firm can select raw peanuts for manufacturing operations from one bin or from several bins (this would produce a co-mingled lot). This allows the firm the ability to trace a specific lot or supplier from a production date. The firm normally receives only bulk tanker trucks of peanuts that are pneumatically unloaded, but occasionally the firm receives raw peanuts in (b)(4) capacity bulk cardboard boxes from (b)(4) companies, such as (b)(4) and (b)(4). These boxes are new and are not reused by the firm to store peanuts used for human consumption. Raw peanuts from the cardboard cartons are dumped into the bulk bins.

Raw peanuts delivered to the firm are accompanied by the USDA Grade and Inspection Certificate and (b)(4) analysis report. The raw nuts are visually inspected by the firm's QC department, and in-house samples are collected for (b)(4) (max. of (b)(4) or sub samples) and (b)(4) (usually about (b)(4)). The firm does not have a minimum or maximum limit for (b)(4) however, the higher the (b)(4) the peanuts would have to (b)(4). According to management, the firm is currently using (b)(4) crop of peanuts in their production.

From the bulk holding bins, the raw peanuts are gravity fed onto a horizontal conveyor which carries the raw nuts to the (b)(4) conveyor that (b)(4) the raw receiving and pre-clean room. Raw peanuts enter into the pre-cleaning room on the conveyor and are transported into the holding bin which discharges the nuts into the (b)(4) which (b)(4). Sticks and other large foreign objects vibrate across the (b)(4) for the equipment and are separated from the peanuts which fall through the (b)(4). The raw peanuts that move across the (b)(4) are discharged into a bucket conveyor which leads into the holding bin supplying raw peanuts to (b)(4) which removes stones, metal objects, etc. Small peanut pieces and broken peanut kernels, etc. that fall through the (b)(4) are also conveyed to the (b)(4). All sizes of peanuts from the (b)(4) are combined and enter a horizontal bucket conveyor which is discharged into the (b)(4). From this (b)(4) the peanuts are conveyed to a bucket conveyor which empties into a (b)(4) in (b)(4) from the pre-cleaning room. Cleaned peanuts are transferred into a holding bin, where peanuts are gravity fed onto the (b)(4).

According to the firm, the peanuts are roasted at an air temperature of (b)(4) for a minimum of (b)(4) minutes. The peanuts are (b)(4) inches in depth on a (b)(4) belt that passes through (b)(4) heating zones and (b)(4) cooling zones. The dwell time is monitored by belt speed, which is measured in Hertz (feet/minute). Maximum belt speed of the roaster is (b)(4) Hertz, equal to (b)(4) feet per minute, (b)(4) minutes per zone. The firm runs the belt speed at (b)(4) Hertz, which is equivalent to (b)(4) minutes per zone, for a total of (b)(4) minutes in the heating zones.

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**Roaster Zones**

Product enters at ambient temperature. H= heating zone C= cooling zone

(b)(4)

When product enters the cooling zones, this (b)(4) the product is not (b)(4) generated from a (b)(4) system blown through a (b)(4) (b)(4) onto the peanuts for a target temperature of (b)(4). The chilled water system is like compressed air coming from a chilled source, but there is no water directly on the product. It should be noted that the area near the exit end of the roaster is not covered. Peanuts fall off the roaster belt (b)(4) onto the (b)(4).

See EXHIBIT # 23 for a copy of the firm's HACCP plan for the peanut butter products, and EXHIBIT # 24 for the firm's HACCP plan for the (b)(4) or Reduced Fat products. The cook time is longer than the CCP of (b)(4) minutes. Ms. Horan stated that they cook longer to achieve the (b)(4). The entire run from end to end is approximately (b)(4) total dwell time in roaster, (includes heating and cooling zones). Original information provided by Mr. Gentle on 2/15/07, was that the peanuts were roasted a (b)(4) minutes. Note that the temperature monitored in the roaster is air temperature, not actual temperature of the product. The peanuts are not probed during roasting, thus the firm can not determine the actual temperature of the peanuts during the roasting stage. Ms. Horan stated that they were not aware of any studies conducted that would validate the temperature of the peanuts while being roasted. The times and temperatures within the roaster are monitored in a control room where the information is electronically charted. The roaster time and temperature charts were not reviewed during the inspection. However, the firm's management was questioned regarding any roaster malfunctions and we were told during the inspection they were aware of none.

The roasted peanuts are transferred from the roaster onto (b)(4) that moves the peanuts to (b)(4) where the peanuts are discharged to the upstairs holding bins, each having (b)(4) capacity. From the holding bins, roasted peanuts are fed into the (b)(4) (b)(4) where the nuts are (b)(4) the peanuts and aspirated from the process flow. The nuts are then conveyed on (b)(4) (b)(4) which reject (b)(4) foreign material, etc. from the product flow. Rejects go through the (b)(4) and any product (b)(4) and rejects are used in (b)(4) (b)(4), (b)(4) peanuts passing through the (b)(4) are transferred to (b)(4) which transports the nuts to (b)(4) which convey (b)(4) roasted

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peanuts to the holding bins on the mezzanine. It should be noted that the firm has open-topped bins in which roasted peanuts are held.

At this point, roasted and cleaned peanuts in the holding bins are gravity fed into a (b)(4) empties into the (b)(4) the primary (b)(4) Once the peanuts enter the (b)(4) the manufacturing operation is considered to be a closed system. During the (b)(4) steps, some heat is generated in the (b)(4) with the product reaching approximately (b)(4) (b)(4) is added to the (b)(4) peanuts during (b)(4) stage. To make crunchy peanut butter, roasted peanuts are diverted in the product flow prior to the (b)(4) and go through the (b)(4) where the peanuts are (b)(4) (b)(4) peanuts are then transferred to a holding bin and stored until added to the process flow prior to filling for the crunchy style peanut butter pro (b)(4) peanuts from the (b)(4) are gravity fed into an enclosed (b)(4) that discharges into the (b)(4) located on the first floor. At this stage, ingredients such as (b)(4) are added to the product. The product temperature drops to approximately (b)(4) at this stage because of the addition of the (b)(4) ingredients. Ingredients such as (b)(4) are added at this stage for the Honey Roasted Products. The weight of ingredients added at the (b)(4) are controlled and monitored by a computer.

The firm has established a separate system for products containing (b)(4) such as the Reduced Fat or (b)(4) products. The addition of ingredients and the mixing of these products are conducted in the (b)(4) room. This area is equipped with (b)(4) which blends the ingredients. After the (b)(4) the product goes to the (b)(4) where the (b)(4) is added, then to the (b)(4) in the (b)(4) room where (b)(4) and (b)(4) are added to the product. The product is then discharges to the (b)(4) (b)(4)

The peanut butter is then conveyed back to the (b)(4) to achieve a creamy texture. During the (b)(4) process, the (b)(4) (b)(4) of the ingredients causes the temperature of the product to increase to (b)(4). Next, the peanut butter is pumped to the (b)(4) (b)(4) During the (b)(4) process the temperature of the product decreases to about (b)(4) Cooled peanut butter is pumped through an (b)(4) located between the (b)(4) section and (b)(4) section. Temperatures generated by the (b)(4) step are approximately (b)(4) Peanut butter is then conveyed from the (b)(4) by a stainless (b)(4) to the (b)(4) At this time, the peanut butter passes through (b)(4) to cool down the product. The cool down temperature after passing through the (b)(4) for creamy and crunchy peanut butter is within (b)(4) (b)(4) before passing to the filling machines. The Honey Roasted peanut butter is (b)(4) of (b)(4) and the (b)(4) Reduced Fat products is (b)(4) The (b)(4) in the (b)(4) is (b)(4) for all products, with the exception of the (b)(4) reduced fat products which are cooled by (b)(4) in the (b)(4)

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Creamy peanut butter is conveyed from the (b)(4) to the fillers. For crunchy peanut butter, chopped peanuts temporarily stored in the holding bin are discharged to the (b)(4) and added to the peanut butter flow at the (b)(4) prior to filling. The firm's whipped peanut butter product is manufactured as described above, but (b)(4) is mixed with the product prior to the filling stage.

The filling room has (b)(4) filling or packaging lines (b)(4) including the filling line for the 55 gallon fiber drums), designated as lines (b)(4). All filling lines are fed from one main line coming from the run tanks, and the lines are split off just before going to the fillers. According to management, crunchy peanut butter products can only be run on line (b)(4) and creamy peanut butter products can be run on lines (b)(4) (b)(4) reduced fat products.

Empty jars are inverted and blown out with compressed air jets prior to filling. The jars are then conveyed to the fillers. Peanut butter is mechanically filled at about (b)(4) fillers which enter the jars and fill from the bottom to the top. The filled jars exit the fillers and are conveyed through the metal detector, then (b)(4) is injected into the head space of each jar prior to the plastic screw cap being applied to each jar. An induction seal is applied to the cap by passing the closed jars under a heat sealing machine, which seals the metal foil liner on the cap to the mouth of the jar. Sealed jars are passed through another metal detector to make sure a foil label is applied. Sealed jars are passed under an ink-jet printer which prints the manufacturing code on the top of each screw cap. Next the jars are conveyed to the labeling machine. Six lb. composite cans are coded on the side of the can approximately 1" from the bottom of the can. Labeled jars are then mechanically packaged into cardboard shipping cases, which are shrink wrapped in clear plastic and case coded. The finished products are initially stored in the firm's warehouse, until ready for distribution. The warehouse is also used for storage of packaging materials (jars, caps, cases, etc.).

**Cleaning/Sanitation Procedures**

There are (b)(4) procedures in this plant. According to Mr. Kimbrell, there is no water used in the plant, with the exception of a small amount of water mixed with (b)(4) used for mopping the floors in the production areas. Any wet cleaning or "clean out of place" (COP) is performed in the wet wash room and any equipment wet cleaned is dismantled and removed to that area for the cleaning. Equipment or utensils such as star-wheels, indexers, screws, screens, buckets, tools, cappers, and filters are taken off of the lines and taken for cleaning in the wet wash room. The equipment removed from the production line is hosed down with water, scrubbed by brushes with (b)(4) cleaner, allowed to air dry, wiped down with (b)(4) wrapped in plastic, and taken back to the production area. For example, the (b)(4) (b)(4) located between the (b)(4) section and (b)(4) section are COP. These (b)(4) are cleaned on a production needs basis not just for routine sanitizing. When (b)(4) are replaced there is a cleaned and sanitized (b)(4) wrapped in plastic and ready for the replacement. Reportedly, any new product contact equipment installed is cleaned and sanitized with (b)(4) at installation, and (b)(4) are taken.

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The buckets or totes used on the production line on the clean side of the plant are removed and cleaned (b)(4) in the wet wash room. The buckets used on the raw side of the operations are only cleaned (b)(4) but these buckets are blown down every (b)(4). Both sets of buckets undergo the same cleaning procedure.

The manufacturing equipment in the closed system, primarily (b)(4) the fillers, are not broken down and entered unless mechanical problems develop. When this happens, the section of the system requiring maintenance is entered and repaired. The equipment is sanitized by wiping down with (b)(4) and reassembling. No water is used for this procedure.

The roaster is cleaned (b)(4) by (b)(4) that is (b)(4) onto the roaster as the (b)(4) (b)(4). The roaster is equipped with (b)(4) at the discharge end, located between (b)(4) of the roaster that is used to (b)(4) from the roaster belt. Water from the (b)(4) onto the (b)(4) or approximately (b)(4) usually (b)(4). Next, the roaster is run for approximately (b)(4) to dry. The (b)(4) is not included in the (b)(4) (b)(4).

**Cleaning and sanitizing supplies** used by the firm include:

(b)(4) is a hand sanitizer used throughout the plant.  
(b)(4) used only in the firm's lab to wipe counter tops; not used in the plant.  
(b)(4) is a liquid sanitizer used on equipment and utensils for COP; after rinsing equipment is wiped down with (b)(4).  
(b)(4) based sanitizer used in the wash room and employee entrance for cleaning floors. Used (b)(4).  
(b)(4) is a cleaner used primarily as a degreaser on frames and machinery. Cleaner is sprayed on and wiped down with (b)(4).  
(b)(4) is a self-foaming cleaner used in the (b)(4) on walls and machinery frames. Used (b)(4).  
(b)(4) cleaner used to polish the outside of tanks. Used (b)(4).  
(b)(4) used as a time released solid-detergent cleaner for the wash room drain. Replaces (b)(4).  
(b)(4) used to clean floors and high oil areas; allowed to air dry. Used (b)(4).  
(b)(4) on the roaster as the (b)(4). Used (b)(4).

See EXHIBIT # 15 for product description and specifications for the above cleaners and sanitizers.

**In-house testing procedures**

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We ask the firm about their in-house testing and sampling procedures. Mr. Kimbrell reported the firm performs micro testing, which consists of (b)(4) on finished product, and the product is not released until tested and found within specifications. Mr. Kimbrell stated that he was responsible for the QA testing and that their sampling of finished product for *Salmonella* was run (b)(4). Mr. Tuncan stated that (b)(4) test that has been approved by the (b)(4). We ask the firm if we could have a copy of the manufacturer's insert for the (b)(4). On 2/16/07, we received a partial package insert (EXHIBIT # 16), therefore, once again we ask for the complete package insert. On 2/17/07, we were given the complete package insert, see EXHIBIT # 17.

Samples of sealed jars are collected across the shift's production and tests are performed on composites from those samples. Sample size for the finished product is (b)(4) per (b)(4) of the product being produced. Containers taken from the same production line are composited. Sample analysis size ranges from (b)(4) of product is removed from each jar. Thus, (b)(4) jars are sampled from a production run then the composite sample size (b)(4) grams. For this composite (b)(4) is made, so (b)(4) (b)(4) would be added to the composite. This composite is incubated for (b)(4). After incubation (b)(4) of the (b)(4) is removed and added (b)(4) and incubated (b)(4) hours at (b)(4). After this incubation (b)(4) is removed from (b)(4) and run on (b)(4). According to Mr. Kimbrell, the product and (b)(4) Investigator Gray inquired if he ever used (b)(4) that the mixture was consistently combined, making sure that all portions of the composite were penetrated. Mr. Kimbrell stated that he had not experienced any problems with this because the (b)(4). I stated that I was curious about the method because the SPI use (b)(4) when conducting *Salmonella* analysis to make sure that (b)(4). It should be noted that no laboratory procedures and/ (b)(4) methods were observed during the inspection.] See EXHIBIT # 18 and 18B for a copy of the 2005 Finished Product Analysis results, and EXHIBIT # 19 for a copy of the 2006 Finished Product Analysis results. No deficiencies were found during the review of these records.

After a quick review of the finished product analytical results, we ask Mr. Kimbrell about the positive and negative controls used during the testing procedures with the (b)(4). He said that he used the controls that were provided with the kit. Investigator Gray then asks if he ever spiked product (peanut butter) with *Salmonella* to confirm that *Salmonella* in peanut butter could be picked up on the (b)(4). Ms. Horan immediately spoke up and said that they do not allow viable *Salmonella* in the firm.

Mr. Kimbrell reported that the firm has (b)(4) swabbing program that includes swabbing (b)(4) different areas in the plant (equipment, overhead walk-way, floors, etc.). See EXHIBIT # 20 for a copy of the Environmental Swab test results for 2005 and EXHIBIT # 21 for the test results for 2006. No deficiencies were found during the review of these records. The locations in the plant that are swabbed (b)(4) are listed on the records. Mr. Kimbrell said that a different spot in each of the (b)(4) locations is swabbed (b)(4).

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He said he has (b)(4) techs that work for him that usually collect the swabs, and he is responsible for running the tests in the lab. The swabs are also run on the (b)(4). The swabs are aseptically collected and each swab is placed in (b)(4) incubated for (b)(4) hours at (b)(4). After incubation, (b)(4) of the culture is removed and added (b)(4) (b)(4) and incubated for (b)(4) hours at (b)(4) C. After this incubation, (b)(4) from the (b)(4) is removed and run on (b)(4).

Mr. Tuncan reported that the firm collects swabs (b)(4) from equipment and food contact surfaces that are run on a (b)(4) which rapidly detects a potential source of microbial contamination. (b)(4) detected, the (b)(4) (b)(4) this procedure tells you if the area is clean, but it is not specific for detecting organisms. According to Mr. Tuncan, if the (b)(4) then the area is recleaned and sanitized. No records pertaining to this procedure were reviewed during the inspection.

(b)(4) is also identified in the finished product and by environmental swabs and recorded on the same analysis report as the Salmonella tests. The (b)(4) a sample is determined by the (b)(4) method, which is recorded as the number of (b)(4) (b)(4) the results give the firm an idea of the general hygiene and sanitation control during the production of peanut butter products.

On the first day of the inspection, we had asked if the firm had encountered any positive *Salmonella* test results in its environmental swabs or finished product testing, and we had been told no by Mr. Kimbrell, the Quality Control Manager. Mr. Kimbrell said they had not had a positive test for *Salmonella* since he has been employed at the firm and he started working there in 2002.

Other finished product tests include (b)(4) (b)(4) and finished prod (b)(4) et weight. On crunchy products th (b)(4) checked. The firm does not che (b)(4) of the finished product.

**MANUFACTURING CODES**

The lot codes for each product are inked in black dot-matrix on the jar lids of each product, with the exception of the product packaged in the 6 lb. composite containers which bears the code on the lower side of each container. The lot codes consists of the plant identification #, year, julian date, 00 space filler, military time, and product line.

For example: "21115251000805A"

2111 =is the Sylvester plant number

5 =is the year 2005



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251= is the julian date

00 = used as space filler, always "00"

0805= is the 4 digit military time of production

A =is the production line (b)(4)

[Note that at one time the firm's plant identifier character began with the letter "S", however, the firm changed to the "2111" around 2004.] There is a slight variation in how the "use by date" is declared on (b)(4) products. The firm's "Use by Date" (b)(4) months from the production date. Code breakdown is the same for both Peter Pan and (b)(4) and is located on the lid. Products exported by ConAgra have a variation in the product code and the labels are specific for name of product not the country the product is shipped to. Products are exported to multiple countries; the international distribution list was copied to a CD and sent to ATL-DO. There are 5 export code variations, see EXHIBIT # 25 .

**MAINTENANCE/REPAIR ISSUES/CONCERNS**

During the inspection we asked the firm if they had experienced any maintenance or repair issues concerning equipment that was directly involved in the production steps. We were told that they have not had any serious problems that they could think of at the time. We discussed the replacement of the roaster, and asked if there had been any problems with the old roaster. Management said that they have had no problems with the roaster other than just routine maintenance. According to Tom Gentle, the roaster belt has been replaced several times, and after each replacement, the roaster is cleaned according to the (b)(4) cleaning procedures as described above in the "cleaning/sanitizing procedures" section of this report. Also, the firm quickly added that they were intending to replace the old roaster before all of this happened, mainly because it was old and had been installed in the plant by the original owners, Seabrook, back in 1975. Reportedly, the firm started construction work in October of 2006 for the placement of the new roaster. The new roaster is manufactured by (b)(4) and the firm anticipates that the new roaster will be installed and operable by May 1, 2007. The firm stated that the new roaster will have (b)(4) more capacity and will produce a more (b)(4)

The Investigators asked the firm if there had been any changes in suppliers or ingredients within the last year that might affect their products. The firm said that they had changed the supplier of the (b)(4) in July of 2006 from (b)(4). According to management, this was a coordinated effort between the two companies because the actual (b)(4) which is located outside, was changed. The exchange was completed on a Saturday during down-time at the firm. The tank was emptied completely, the valve was turned off, and then the tank was exchanged. The exchange was completed within one day. The tank is not new, it is reconditioned. A (b)(4) line delivers (b)(4) into the plant via pipes with the pressure of (b)(4) psi. The (b)(4) is withdrawn as a (b)(4). The (b)(4) is distributed to (b)(4) points in the plant where used (i.e. (b)(4) and storage tank (b)(4) product containers). Management stated that the valve was turned off during the exchange;

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however, the tanks could have been changed with out the valve being shut. The firm is not aware of any instances where water could have entered the system.

(b)(4) horse power air compressors supply air to the dryers, where the air is filtered. (b)(4) automatic air surge tanks, each with moisture drains, provide bursts of compressed air to the filling lines. The (b)(4) line is equipped with it own independent air-flow system (b)(4) from a local blower that is monitored and filtered at this location. The firm said that the surge tanks have not been changed; however, they reported that they did (b)(4) and it was replaced in October of 2006. They stated that this was (b)(4) and prior to the surge tank, so there was not a problem. (b)(4) environmental swabs do not include (b)(4)

(b)(4)

We discussed if there had been any leaks or if there was the possibility of water coming into contact with the (b)(4) reduced fat product that passes through the (b)(4) votators. The firm explained that this is a closed system, where the peanut butter flows through a cylindrical tube surrounded by a larger cylinder where the (b)(4). The interior piping of the votators is a food contact surface, with the pipe passing through a cooling medium to effect the temperature change. According to Mr. Dave Taylor, in a closed system such as this, there will naturally be a loss of water by evaporation, and there is no way to tell the difference between a leak and evaporation. However, the temperature of the product is observed throughout the votator by a temperature probe that is monitored in the control room. If (b)(4) change is detected it would indicate a leak. The (b)(4) temperature fluctuates between (b)(4). The firm said that the (b)(4) circulation for all votators is about (b)(4)s./hr. The firm said that pressure differential of the water and the product would also signify a leak. Management indicated that the pressure on the product side is high (b)(4) ps. psi) than the pressure on the water side (b)(4) ps psi); therefore, if there was a leak you would have product in the water, not vice versa. Included in that explanation was a comment that the cooling tower water is checked for clarity on a regular schedule and finding cloudy or milky water would indicate a leak or a problem.

According to the firm, their bulk water tank, which is equipped with a float bulb, is filled from a municipal water source. When the water level drops, the float valve would be triggered to add water. Water is treated between the bulk tank and votators cooling system. The firm reported that they have had no breakdowns on the chiller system. Mr. Taylor stated that the water is treated with an (b)(4) produced by (b)(4) the firm provided us with records from (b)(4) about treatment materials added to cooling water in the chilled water system that is pumped through the votators/heat exchangers on the peanut butter line that use (b)(4) see EXHIBIT # 26 for a copy of these records.

We inquired then as to how this equipment is cleaned. Mr. Dave Taylor reported that the votators are dismantled, cleaned and sanitized, and that documentation would record this procedure. Investigator Douglas then asked if the equipment was swabbed or checked in some manner to validate the effectiveness of the cleaning, and if the firm had records to verify the cleaning and validation.

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Reportedly, the firm maintains a line entry program for documenting any equipment on the closed production line that is dismantled and removed, cleaned and sanitized, and placed back onto the line. On 2/20/07, we ask to review these records. On 3/2/07, Mr. Ehret provided the Line Entry Permits from January of 2006 to the present date to Investigator Gray for a review. [Note that we were not given a copy of these records, they were available for review only.] The Line Entry Permits are completed when maintenance has to go into the "closed" portion of the product line, basically the part from the (b)(4). These records document information such as the service performed, GMP's and safety regulations checks, who performs work, date, and the sanitizer used. The records reviewed consisted only of maintenance work involving the replacement of valves, balls, seats, and pistons adaptors for (b)(4) and standard maintenance of the (b)(4). I asked Mr. Ehret if it was typical to replace parts on the (b)(4) over (b)(4) months, and he informed me that this was a common procedure conducted for the maintenance of the (b)(4).

We also asked for records that would document the cooling tower checks or any maintenance work in 2006. We were told that these checks should be part of the preventative maintenance records. We were not provided any other records pertaining to the cooling tower checks during the inspection. On 3/2/07 the last day of the inspection, Mr. Ehret informed Investigator Gray that Ms. Horan was gathering this information; however, she was currently traveling back to CA and he was not aware of any information she might have obtained at this time. He stated that he would let Ms. Horan know that we continued to ask for this information, and he would tell her to contact Investigator Gray about any records or information she had found. As of 3/29/07, Ms. Horan has not contacted the Investigators with this information.

We inquired if the firm was aware of any (b)(4) valves used in any of the processing equipment. We explained that we were trying to determine if these valves could be a potential source of product residue. The firm said that they have (b)(4) valves in many of the vessels in the closed portion of the system and that the (b)(4) valves operate the sensors that monitor the product level in the vessels. The (b)(4) is used as a level transmitter that works from the pressure of the product, and indicates the tank level to a computer. Mr. Malinowski explained that all (b)(4) valves used in the firm's systems are (b)(4) and every tank that has a sensor has a (b)(4) valve. The valve has (b)(4) (b)(4) diameter) with (b)(4) (b)(4) product is pushed against the (b)(4) to give a signal of the tank level. Product touches only the (b)(4), and all elements that come into contact with the product are made of (b)(4) (b)(4) are used, so no abrasions or scratches would be created on the (b)(4). Management stated that they were not sure how many (b)(4) valves they had in their equipment or the manufacturer of these valves, but they would work on compiling a list for us. The firm does not routinely keep such a record; therefore, it took several days to collect this data requested. On 3/2/07, Mr. Ehret provided me with a list of the location and manufacturer of (b)(4) gauges (valves) in the plant. [Note that this record was provided only for review, no copies were provided to the Investigators.]. According to the document:

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(b)(4) valves are located on equipment in the upstairs area (b)(4) addition), the valves are manufactured by (b)(4) (b)(4)  
(b)(4) valves are located in the downstairs tank room, the valves are manufactured by (b)(4)  
(b)(4) valves are located in the (b)(4) feeds the (b)(4) the valves are manufactured by (b)(4)  
(b)(4) valves are located in the (b)(4) the valves are manufactured by (b)(4)  
(b)(4) valves are located in the (b)(4) the valves are manufactured by (b)(4)

During the inspection, we asked management if they were aware of any employee illnesses that might have contributed to product contamination. The firm presented us with a 1 ½” thick binder filled with calls made by employees for being tardy, sick, attending funerals, etc. We explained that we only wanted to know if they maintained employee health records that might identify a specific time period or employee that could have contributed to a microbial contamination in the plant. On 2/26/07, Ms. Horan informed us that she had not actually sat down and reviewed the employee illness records. She said that as a team they would address any data that looked significant. On 2/28/2007, Mr. Ehret informed me that they had pulled the data concerning employee illnesses, and they had not found any trends or any thing that could be connected.

**CONSUMER COMPLAINTS**

On 2/14/07, we asked the firm if they had received any consumer complaints that might be connected to the current situation, and management replied that they were not aware of any complaints, but Ms. Horan stated that she would look into it and let us know what she found. On 2/20/07, Ms. Horan informed us that the corporate office was supposed to be printing a list of consumer complaints they had received within the past year that had similar allegations. She explained that ordinarily consumer complaints are handled by the corporate office because their product labels list the address and toll free phone # for the office in Omaha, NE for any questions or comments, thus the Sylvester plant would not be contacted directly by consumers.

At this time, information concerning a consumer complaint received in December of 2006, Reference # 051314249A, for Peter Pan Reduced Fat Creamy was inquired about. The complainant reported that her husband and two grandchildren became ill with diarrhea, vomiting, and unknown fever after eating peanut butter on 2 separate occasions. The consumer called ConAgra in December and ConAgra sent her a pre-postage paid envelope for her to send the product to them so that they could do laboratory testing on the product. The product was mailed to ConAgra on 12/12/06. Reportedly, the consumer called ConAgra several times for the test results, but they had no information to give her. We ask management if they were aware of the complaint, and Ms. Horan informed us that to the best of her knowledge no one at this plant was aware of this complaint. We gave Ms. Horan the consumer’s name and the reference #, and ask if she could collect some information on the episode and give us an idea of the outcome. Later that day, Ms. Horan informed us that she had discussed the above complaint with Don Jones, Sen. Director of Food Safety and

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Quality, and he said that at the time of this complaint it was not their policy to analyze opened jars of product because they didn't know if the product had in fact made the consumer sick or if the consumer had contaminated the product after it was opened. Also, we asked if they kept retain samples of product shipped to them by consumers, and she said that she would check.

On 2/21/07, management informed us that they had this particular complaint in their records and they did maintain a retain sample. Ms. Horan stated that they planned on analyzing this opened product. The results from the test were not released or discussed with the investigators. On 2/23/07, we received a list of consumer complaints (alleged illness) compiled by the corporate office for the time period of 1/1/06 to 2/14/07, see EXHIBIT # 27. The firm was not sure if they had retained samples for any of the other consumer complaints or what, if any, follow-up was conducted. No other complaints were discussed during the inspection.

**OCTOBER 2004 POSITIVE SALMONELLA RESULTS**

On the first day of the inspection, we had asked if the firm had encountered any positive *Salmonella* test results in its environmental swabs or finished product testing, and we had been told no by Mr. Kimbrell, the Quality Manger. On 2/23/07, Mr. Kimbrell provided to us copies of the firm's swab testing results for 2005 and 2006. Investigator Douglas asked him if he was a microbiologist and he replied yes. Investigator Douglas then repeated to him what he had told us earlier, that he had been here since 2002, and he said yes. Mr. Kimbrell was then asked if he would remember or know of any positive test results, and he said yes. Investigator Douglas once again asked if the firm had ever had any swabs or finished product samples positive for *Salmonella*, and Mr. Kimbrell said no, but he appeared to hesitate in his answer. Investigator Douglas voiced that he detected some hesitation in his answer, and asked had there been any positive tests of anything. At this time, Ms. Horan immediately said that the firm had 2 positive *Salmonella* tests in October of 2004, but none of the product ever got out. She further explained that the firm had 2 positive *Salmonella* test results from peanut butter samples, however, the product involved was destroyed and none of it was released from the plant. She said the firm performed extensive swabbing and testing, but they were not able to identify the source.

Investigator Douglas told Ms. Horan that this sounded familiar to him in that during the February 2005 inspection he had conducted at the firm involved consumer complaints FDA had received, including an anonymous complaint indicating the firm had a "micro problem". He said that during the 2005 inspection he was told only that the firm had placed product on a micro hold and that the product was destroyed. Ms. Horan once more stated that none of the product got out.

Ms. Horan later explained that they thought that our questioning earlier in the inspection and Mr. Kimbrell's negative response to us had been in reference only to environmental swab testing. We told her that was not the case, and she said they obviously misunderstood. She said that their instructions from the very start of the inspection from the corporate office were to be completely open and honest with FDA. She said that the hesitation in Mr. Kimbrell's response resulted from the stress under which they were operating. She said he was supposed to run all of the questions from

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FDA through her before answering, so that was the reason she jumped in so quickly to clarify. She said she wanted us to know they intended to be completely open, and we told her we understood the stress everyone was under.

Investigator Douglas repeated to Ms. Horan his concern over the October 2004 incident. He told her he had attempted to follow-up an anonymous complaint regarding micro problems with (b)(4) the previous Plant Manager, a (b)(4) the previous Quality Manager, during the inspection in February of 2005. (Refer to History section of this report for previous inspection summary.)

Investigator Douglas said that they had checked with their corporate office and he was told only that the firm had placed some product on a micro hold and the product had been destroyed. He asked why they would not have reported the reason, and Ms. Horan said she couldn't answer that. He told her that considering what has since happened, he felt we had no choice but to review whatever information the firm had that would assure us the problem in October of 2004 had been contained. She said all she knew at the moment was that one of their experts took numerous swabs, but they never determined the source, and an extensive clean-up was performed. Ms. Horan reported that micro tests were run on finished product and environmental swabs, and that the *Salmonella* found was speciated in Omaha, but she did not recall it being *S. Tennessee*. Ms. Horan stated that she would ask the corporate office if and what information we could review concerning the 2004 occurrence. On 2/28/07, we received a summary of the October 2004 positive Salmonella test results from Mr. Don Jones, Sr. Director Enterprise Quality and Food Safety, EXHIBIT # 28 .

**ADDITIONAL INFORMATION**

On 2/26/07, we were notified by Ms. Chris Horan that they would be requiring a written request from the FDA before they could provide certain requested information. Ms. Horan indicated that the USDA normally provided such a request, and their legal department is requesting the same from us, so that this request would serve as a means of tracing the records provided to the FDA. This included information related to the findings of Salmonella during October of 2004 in finished product. Ms. Horan said that the firm usually requires such a written request, but they had been forgoing it up until now for expediency; however, some of the corporate people were not exactly sure what records we were asking for, and they needed a specific written request. She said that she thought the sticking point was the information concerning employee illnesses, and some of the corporate people were unfamiliar with some of the maintenance related issues, such as the cooling tower questions. We asked Ms. Horan who provided their legal counsel, and she reported that Mr. Tracy Beck in their corporate office was responsible for their legal department. We explained that we do not normally issue written requests and we would have to discuss this with our superiors in our district office before proceeding.

When we arrived at the firm on 2/28/07, Ms. Horan provided us with some of the records and information we had verbally requested earlier. The records were accompanied with a memo from Don Jones concerning these requests, EXHIBIT # 30.

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On 2/26/07, Ms. Horan had discussed that they are trying to prepare the complete cleaning procedures for the plant. She said that they are planning on doing a complete HACCP concept cleaning, and they have started ordering supplies. Also, she said that the results from the environmental swabs and raw ingredient samples will impact the cleaning. Ms. Horan said that the HACCP plan will be re-assessed, and the firm's procedures will be reviewed and improvements made. She commented that their cleaning will be based on their test results as well as the FDA's. Ms. Horan stated that as soon as we are finished in the plant they will assemble their team and see where to start. During the down time at the plant, the employees have been receiving food sanitation training off-site. Management said that they are trying to raise awareness of all employees for food safety and food micro.

**SAMPLES COLLECTED**

On 2/15/07, we were joined by Chauncey A. Stephens and William (Bill) K. DuCloux, Microbiologists from the Southeast Regional Lab. The analysts collected environmental swab samples by aseptic technique on 2/15, 2/16, and 2/17. The analysts also assisted us with raw ingredient sampling and shipment of samples. Swab samples were collected with SpongeSicle 10ml Neutral Buffer, SSL-10NB produced by Biotrace International.

During the collection of environmental swabs throughout the plant, the firm was observed to collect their own samples, swabbing the exact area as the SRL analysts, and using the same subsample numbers. The location of each swab sample collected was recorded by the Investigators and also by the firm. On 2/17/07, the firm provided us with a description of each swab location collected. This list is attached to each collection report, included with this report, for the environmental swabs collected. The firm's swab samples were collected by Mr. Tuncan and Mr. Kimbrell. The firm used

(b)(4)  
(b)(4) was noted that the firm was using swabs that had an expiration date of 2005/5, see EXHIBIT #29. Investigator Gray asked Mr. Tuncan if they were using the same set of swabs that they normally used to collect the (b)(4) environmental swabs, and he said that he thought that it was the same swabs. When the expiration date of 2005 was pointed out, Mr. Tuncan stated that it didn't really matter. On 2/21/07, we noted that the firm had purchased several packs of (b)(4) swabs (b)(4) used by the FDA analysts. The firm took photographs of each location, and noted the location of each swabbed area. During the collection of each finished product sample, the firm was observed to collect duplicate samples, selecting jars from the same case. The firm reportedly shipped their samples to (b)(4) for Salmonella analysis. The sample results collected by the firm and analyzed by (b)(4) were not discussed with the Investigators during the inspection.

It should be noted that during the inspection, the firm did not dismantle any equipment that is not normally cleaned out of place in the wet wash room (i.e. (b)(4)). Mr. Gentle stated that they were waiting on our results to determine what and how deep to clean, therefore, if the results were negative, then they would not tear down anything out of the normal COP. We explained that we had planned on collecting environmental swabs in and around the equipment in the closed system, but if they were not already planning on tearing down this equipment, we would just collect

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swabs of areas within reach. Mr. Gentle stated that some of the equipment tear down and replacement would take weeks to accomplish, so they preferred to wait for the lab results.

The following samples were collected during the inspection and transported to SRL for Salmonella analysis. A copy of the Collection Report for each sample is attached to this report.

Collected on 2/14/07:

**Sample #366079** consisted of 15/18 oz. jars of Peter Pan Creamy Peanut Butter, lot code " PRD 11/09/06 EXP 11/09/08 ICOMTRADE" (this lot was manufactured for export);

**Sample # 366080** consisted of 15/18 oz. jars of (b)(4) Crunchy Peanut Butter, lot code "2111634200 BEST BY 06 08 08";

**Sample # 366076** consisted of 15/22 oz. jars of Peter Pan Crunchy Peanut Butter, lot code:2111632000 BEST BY MAY162008".

Collected on 2/15/07:

**Sample #366077** consisted of 25 aseptically collected environmental swabs of various areas and equipment throughout the plant;

**Sample # 366078** consisted of 25 aseptically collected environmental swabs of various areas and equipment throughout the plant;

**Sample # 389113** consisted of 24 aseptically collected environmental swabs of various areas and equipment throughout the plant;

**Sample # 389114** consisted of 25 aseptically collected environmental swabs of various areas and equipment throughout the plant.

Collected on 2/16/07:

**Sample # 366081** consisted of 23 aseptically collected environmental swabs of various areas and equipment the plant;

**Sample # 366082** consisted of 12/approximately 4 oz. subsamples of Peter Pan (b)(4) Blend, lot 10701124;

**Sample #366083** consisted of 6/approx. 4 oz subsamples of (b)(4) Concentrate, Lot No. 061206P;

**Sample #366084** consisted of 10/approx. 4 oz. subsamples of (b)(4) blend, lot 10701123;

**Sample #366085** consisted of 10/approx. 4 oz subsamples (b)(4) Lot No. KFRTS;

**Sample #389115** consisted of approximately 12 ounces total of "Peter Pan" (b)(4) lected in approximately equal portions from ports in powder room;

**Sample #409450** consisted of approx. 4 ounces of (b)(4) from port in powder room;



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**Sample #409451** consisted of approx. 8 ounces total of (b)(4) collected in approx equal portions from ports on each bulk (b)(4) tank;

**Sample # 409452** consisted of 10 aseptically collected environmental swabs of empty jars taken at peanut bu

**Sample # 409453** consisted of 10 aseptically collected environmental swabs of jar lids taken at peanut butter

**Sample #409454** consisted of 7/approx. 4 oz. subsamples (b)(4) lot # SG6K7052A.

Collected on 2/17/07:

**Sample #409607** consisted of 10 aseptically collected environmental swabs of various areas and equipment throughout the plant;

**Sample #409455** consisted of approx. 20 ounces total of (b)(4) collected in approx. equal portions from 5 bulk totes, lot 0257D;

**Sample #409456:** consisted of approx 8 ounces total of (b)(4) collected from bulk tote bags, Lot S031H.

**Sample #409457** consisted of 4/approx. 4 oz. subsamples of (b)(4) from bulk hopper to (b)(4)

**Sample #409458** consisted of 3/approx. 4 oz. subsamples of (b)(4), Lot (b)(4)

**Sample #409459** consisted of 5/approx. 4 oz. subsamples of (b)(4) Lot W6191;

**Sample # 409606** consisted of 8/approx. 4 ounce subsamples of (b)(4) from bulk tote bags; Lot B0367.

Collected on 2/21/07:

**Sample #409786** consisted of 15/18 oz jars of Peter Pan Honey Roast Creamy Peanut Butter, coded "2111703700";

**Sample #409787** consisted of 15/18 oz jars of Peter Pan No Sugar Added Creamy Peanut Butter Spread, coded "2111704400";

**Sample #409788** consisted of 15/18 oz jars of (b)(4) reduced Fat Peanut Butter Spread, coded "2111703000";

**Sample #409789** consisted of 15/18 oz jars of (b)(4) Creamy Peanut Butter, coded "2111700600";

**Sample #409790** consisted of 15/28 oz jars of (b)(4) crunchy Peanut Butter, coded "2111700500";

**Sample #409791** consisted of 15/28 oz jars of (b)(4) Creamy Peanut Butter, coded "2111702000";

**Sample #409792** consisted of 15/18 oz jars of (b)(4) reduced Fat Peanut Butter Spread, coded "2111702900";

**Sample #409793** consisted of 15/28 oz jars of Peter Pan Honey Roast Creamy Peanut Butter, coded "2111703700";

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**Sample #409794** consisted of 15/17.6 oz jars of Peter Pan Plus Creamy Peanut Butter, coded "2111704500";

**Sample #409795** consisted of 15/18 oz jars of Peter Pan Creamy Peanut Butter, coded "2111704400";

**Sample #409796** consisted of 15/18 oz jars of Peter Pan Crunchy Peanut Butter, coded "2111703900";

**Sample #409797** consisted of 15/18 oz jars of Peter Pan Honey Roast Crunchy Peanut Butter, coded "2111704500".

Collected on 2/26/07:

**Sample #409798** consisted of 11/approximately 1 lb subsamples of raw, shelled peanuts collected from lots stored in raw storage bins number (b)(4). The subs collected were numbered according to the storage bin each sub was collected from.

Collected on 3/2/07:

**Documentary Sample # 409799** documents the interstate commerce (b)(4) cases of Peter Pan Products shipped from ConAgra Grocery Products, Sylvester, GA to (b)(4) 2/14/07.

**CLOSING DISCUSSION**

Mr. Earl Ehret and Ms. Tabitha Giddens were the only members of management present during the closing discussion. The FDA-484 was issued to Mr. Ehret, and the FDA-463a was read and signed by Mr. Ehret. The Line Entry Permits from 7/31/06 to the present date and the listing of the manufacturer's and location of (b)(4) valves in the plant were reviewed at this time. Mr. Ehret stated that they had started some surface cleaning, but the complete cleaning plan was still not finalized.

I told Mr. Ehret that a FDA-483, Inspectional Observations report, would not be issued at this time; however, the information gathered during the inspection would be documented in a report, which would be reviewed by the ATL-DO Compliance Branch, and FDA could pursue legal actions to achieve compliance. Mr. Ehret stated that he understood. I explained to management that the inspection was finished, and their cooperation throughout the inspection was appreciated.

**EXHIBITS**

EXHIBIT # 1: Organizational chart for ConAgra Foods; 1 page

EXHIBIT # 2: Distribution/inventory centers that receive finished product from the firm; 1 page

EXHIBIT # 3: Product inventory location as of 2/17/07 for products shipped from this plant; 14 pages

EXHIBIT # 4: Product codes or SKU numbers used by the firm to identify product

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- types and sizes; 3 pages
- EXHIBIT # 5: Product labels; 19 pages
- EXHIBIT # 6: Label for product packaged in 55 gallon drums; 1 page
- EXHIBIT # 7: Letter of Inspection from the drum supplier; 1 page
- EXHIBIT # 8: Labels of raw ingredients on hand at the plant during the inspection; 24 pages
- EXHIBIT # 9: Certificate of Analysis (COA) for (b)(4) and (b)(4) 9 pages
- EXHIBIT # 10: Supplier and list of raw ingredients/materials used in the firm's manufacturing operations; 3 pages
- EXHIBIT # 11: Shipping Ticket and Hold notice for the shipment of 2 pallets of "wet" jars shipped to the firm on March of 2006; 2 pages
- EXHIBIT # 12: List of the lubricants used in the plant; 2 pages
- EXHIBIT # 13: Production code for suspect jars of peanut butter collected from consumer's involved in Salmonella outbreak; 1 page
- EXHIBIT # 14: Finished Product Analysis results for suspect production codes; 10 pages
- EXHIBIT # 15: Description and specifications for the cleaners and sanitizers used in the plant; 23 pages
- EXHIBIT # 16: Partial package insert for (b)(4) received on 2/16/07; 5 pages
- EXHIBIT # 17: Complete package insert (b)(4) received on 2/17/07; 10 pages
- EXHIBIT # 18: Finished Product Analysis results for 2005; 255 pages
- EXHIBIT # 18B: Finished Product Analysis results for 2005 (additional pages); 10 pages
- EXHIBIT # 19: Finished Product Analysis results for 2006; 241 pages
- EXHIBIT # 20: Environmental Swabs analysis results for 2005; 12 pages
- EXHIBIT # 21: Environmental Swabs analysis results for 2006; 12 pages
- EXHIBIT # 22: Plant diagrams of the firm; 3 pages
- EXHIBIT # 23: Firm's HACCP plan for Peanut Butter products (Peter Pan and (b)(4) (b)(4) pages
- EXHIBIT # 24: Firm's HACCP plan (b)(4) and Reduced Fat Peanut Butter Spread (Creamy and Crunchy); 16 pages
- EXHIBIT # 25: Product Reference Sheet for Exported Products; 5 pages
- EXHIBIT # 26: Cooling Tower Service Reports; 5 pages
- EXHIBIT # 27: Complaint Summary Report for Peanut Butter; 2 pages
- EXHIBIT # 28: Salmonella Positive results summary for October 2004; 13 pages
- EXHIBIT # 29: Culture Swab used by firm to collect environmental swabs; 1 page
- EXHIBIT # 30: Memorandum from Don Jones, Sr. Director of Enterprise Food Safety and Quality,

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dated 2-28-07, regarding requested documents: 1 page.

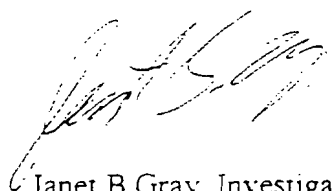
**ATTACHMENTS**

Attachment A: CDC memorandum's for Salmonella Tennessee Outbreak

FDA-482, Notice of Inspection: 2/14/07 and 2/15/07

FDA-484, Receipt for Samples: 2/14/07 and 3/2/07

Collection Reports for Samples collected during EI



Janet B Gray, Investigator

Jackie M. Douglas, Investigator