

Establishment Inspection Report

ConAgra Foods
Sylvester, GA 31791

FEI: 1038538
EI Start: 08/20/2007
EI End: 08/23/2007

SUMMARY

The current inspection of this peanut butter manufacturer was conducted as per a directed assignment from ATL-DO to conduct a follow-up inspection of this firm. This was a joint inspection with the Georgia Department of Agriculture. The previous inspection was conducted as per 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. Samples collected during the 2/14/07-3/2/07 inspection revealed the presence of *Salmonella Tennessee* in environmental swabs and finished product. The firm initiated a product recall for Peter Pan and (b)(4) Peanut Butter products manufactured at the plant.

This firm has been shut down since 2/14/07 until 8/6/07 for extensive repairs to the roof, installation of new equipment, additions and renovations for the raw peanut storage areas, cleaning/sanitizing rooms, roaster area, tank room, packaging area, and a cleaning and sanitizing of the entire plant including floors, walls, ceilings, and equipment. Currently the firm is only producing Peter Pan Creamy Peanut Butter in 18, 28, and 40oz. containers, and Peter Pan Crunchy Peanut Butter in 40 oz. container (b)(4) is also producing 18, 28, and 40 oz. jars Peter Pan Creamy and Crunchy Peanut Butter under a temporary contract with ConAgra Foods.

The focus of the current inspection was to observe the corrections and renovations performed by the plant since the previous inspection. Samples collected during the inspection, including finished product, raw peanuts, and 124 environmental swabs. See "Samples Collected" section at the end of this report for sample numbers and descriptions.

A FDA-483, Inspectional Observations, was issued to management at the conclusion of the inspection for the following deficiencies: effective measures are not being taken to exclude pests from the processing areas and protect against the contamination of food on the premises by pests; failure to store cleaned and sanitized portable equipment in a location and manner which protects food-contact surfaces from contamination; and failure to provide safety-type lighting fixtures suspended over exposed food. These objectionable conditions were corrected and verified before the close of the inspection.

The firm did not allow me to take photographs due to their corporate policy concerning trade secrets, thus this was the only refusal encountered during the inspection.

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ADMINISTRATIVE DATA

Inspected firm: ConAgra Foods
Location: 101 S. Seabrook Dr.
Sylvester, GA 31791

Phone:

FAX:

Mailing address:

Dates of inspection: 8/20/2007, 8/21/2007, 8/22/2007, 8/23/2007

Days in the facility: 4

Participants: Janet B Gray, 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. Individuals responsible for operations and QA at this location were identified as Earl G. Ehret, Plant Manager, and Joey Kimbrell, Quality Control Manager.

INTERSTATE COMMERCE

The firm has started shipping finished products to various distribution centers located throughout the country from this plant. See EXHIBIT # 1 for a copy a Bill of Lading #004633779M, Shipping Manifest, and Packing List/Loading Sheet, dated 8/21/07, for the shipment of (b)(4) cases of 40 oz. Peter Pan Creamy Peanut Butter to (b)(4) located in (b)(4).

JURISDICTION

Currently, the firm is manufacturing 18 oz. Peter Pan Creamy Peanut Butter on filling line/production line (b)(4) 28 oz. Peter Pan Creamy and 40 oz. Peter Pan Crunchy and Creamy on production line (b)(4). The plant is equipped with (b)(4) additional production lines (b)(4) but these lines are currently not in use. According to management, other Peter Pan products will be added to the

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production line at various stages. According to management, crunchy peanut butter products can only be run on lines (b)(4) and creamy peanut butter products can be run on lines (b)(4). (b)(4) is used to fill 18 oz. jars, (b)(4) is used to fill 22, 28 and 40 oz. jars, (b)(4) is used to fill 18, 22, 28, and 56 oz. jars; and (b)(4) is used to fill 6 lb. cans of creamy and 18 and 28 oz. jars of smart choice/reduced fat products.

Projected time lines for future products include the following:

Peter Pan Creamy (28oz.) on filling line (b)(4) projected date of 9/3/07

Peter Pan Creamy Twin Pack for (b)(4) (40 oz.); projected date of 9/3/07

Peter Pan Creamy No Sugar Added Peanut Spread (18 oz.); projected date of 11/5/07

Peter Pan Creamy Smart Choice/Reduced Fat (18 and 28 oz.); projected date of 11/12/07

Peter Pan Honey Roast (18 and 28oz.); projected date of 11/26/07

Peter Pan Plus Vitamins & Minerals (18 oz.); projected date of 11/26/07

Peter Pan Whipped (18 oz.); projected date of 1/7/08

Peter Pan Peanut Butter (56 oz.); projected date of 1/14/08

New product labels have been produced. See EXHIBIT # 2 for the product labels provided by the firm during the inspection. Management stated that all of the products will have a new label, but the new labels will not be ordered until the actual products are being produced. Also, the shape of the plastic jars have been slightly altered, so that the top of the plastic jar does not angle in towards the opening as much as the previous containers. The lid size and colors will remain the same.

According to Mr. Ehret (b)(4) is attaching the same new labels to the product manufactured for ConAgra Foods. He said that the only difference in the labels is that the (b)(4) (b)(4) Product labels are a "full wrap around" (goes all the way around the container), whereas the labels applied to the product manufactured at ConAgra cover approximately 3/4 of the area on the side of the containers. I asked if this was intentional, and Mr. Ehret said no, their machines were just not set up to apply a full wrap around label.

During the inspection, the firm was using raw, shelled peanuts received from (b)(4) in (b)(4). The firm receives raw peanuts in bulk tanker trucks that are pneumatically unloaded into the firm's raw peanut holding bins. Each lot of raw peanuts is accompanied with a USDA Certified COA (certificate of analysis) for Aflatoxin (b)(4) less), which is reviewed prior to releasing the peanuts for processing.

Other raw ingredients used for the manufacture of peanut butter products at this plant include (b)(4) (b)(4) and (b)(4). Raw materials are purchased from approved suppliers, and each lot of materials is accompanied by a COA (certificate of analysis). The firm does not conduct in-house testing of raw materials. The firm has not changed the raw materials suppliers since the previous inspection. The

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only change involves the removal of the bulk (b)(4) tank located on the outside of the plant. Currently, the firm is using (b)(4) bags (b)(4) instead of (b)(4). Mr. Ehret stated that the firm will probably install a new bulk (b)(4) tank in the near future. (b)(4) are received in bulk tankers and stored in bulk silos. Other ingredients are received in smaller, individual size containers and stored in the dry materials area and the manual dump area.

Packaging materials used by the firm include caps, jars, trays, cans, jar seals, and labels. The supplier of the packaging materials has not changed. Materials are visually examined upon receipt for damage and defects. Labels are inspected upon receipt to verify the correct product information (i.e. allergen declaration). As jars come into the warehouse, they are checked for (b)(4) (b)(4). The firm does not receive a COA or conduct in-house testing on jars and caps.

(b)(4) refined at (b)(4) purity, stored in pressurized cylinders, is used in the plant as a processing aide for the head space of jars and holding bins. The (b)(4) system is equipped with a (b)(4) at the filling stations.

There is no (b)(4) added as an ingredient for the products manufactured at this plant. The firm has city water and it is used only for COP equipment and mopping floors.

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITY

At the initiation of the inspection, 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. Also, "Alert" information was provided to Mr. Ehret. Present also at this time was A. Joseph (Joey) Kimbrell, Quality Manager, and Joseph Elrefaie, Corporate Senior Supply Quality Specialist. I explained the purpose of my visit, and that this would be a joint inspection with Bill Jones, GDA Inspector. In addition, I told management that samples would be collected during the inspection, which would include approximately 100 swabs from various locations in the plant. I informed them that two analysts from the Southeast Regional Lab would be joining the inspection later in the day, to assist with the sample collections. Shortly after the start of the inspection, Chauncey A. Stephens and William (Bill) K. DuCloux, Microbiologist from the SRL, joined the inspection. An additional FDA-482 was issued at this time.

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. Mr. Ehret provided accompaniment throughout the inspection, and access to records requested. The corporate office gave the final authorization allowing us to review or receive a copy of records requested during the inspection and Mr. Ehret served as the liaison for the corporate office. It should be noted that each set of records provided to me during the inspection was accompanied by a cover sheet from Mr. Ehret, see EXHIBIT # 4. The FDA-483, Inspectional Observations, the FDA-482, Notice of Inspection, and the FDA-484, Receipt for

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Samples, was issued to Mr. Ehret. FDA correspondence should be sent to Mr. Earl Ehret at the plant's address.

Mr. A. Joseph Kimbrell, Quality Control Manager, is responsible for all quality control functions in the plant, including, cleaning and sanitation procedures and finished product and environmental swabs collections. Mr. Kimbrell provided intermittent accompaniment during the inspection. Mr. Kimbrell provided information pertaining to new laboratory procedures, cleaning supplies, and the firm's new sanitation program.

Joseph Elrefaie, Corporate Senior Supply Quality Specialist, was present during the inspection. Mr. Elrefaie stated that he has been at this location for several weeks assisting the QA department and overseeing sanitation procedures. He reports to the corporate office in Omaha, NE on a routine basis. Mr. Elrefaie provided accompaniment throughout the inspection and answered cleaning and sanitation questions not otherwise observed.

Leonard Caplan, Quality Manager for ConAgra's Green Bean Plant located in Fort Worth, TX, joined the inspection on 8/21/07. He provided intermittent accompaniment throughout the remainder of the inspection.

Benjamin R. Warren, Ph.D., Senior Corporate Microbiologist in Omaha, NE, joined the inspection on 8/21/07. Dr. Warren provided accompaniment throughout the remainder of the inspection, and he collected the firm's swab samples taken during the inspection. He provided information pertaining to sanitation and cleaning procedures.

Paul A. Hall, Ph.D., Vice President of Global Food Safety in Omaha, NE, joined the inspection on 8/22/07. Dr. Hall stated that he personally conducted the collection of approximately (b)(4) environmental swabs collected within the past few weeks at the plant. He stated that he was recently hired by ConAgra to oversee the Food Division of Research, Quality, and Innovation within ConAgra. Dr. Hall was present during the inspection only on 8/22/07. He was also observed to collect swab samples for the firm during the inspection.

I was briefly introduced to Kathy Surber, Food Safety and Regulatory Compliance Manager, who was working in the firm's laboratory during the inspection. Ms. Surber reports to the Omaha, NE office, and she stated that she is temporarily assisting the lab techs during the initial start up of operations.

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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 first shift runs from (b)(4) and the second shift from (b)(4). Sanitation operations are staffed 24 hours per day, with any major clean-ups performed during the down time from (b)(4) and on Sundays. The firm has (b)(4) hourly and (b)(4) salary employees.

Changes in Operation and Equipment/Corrections

During the current inspection, I observed numerous changes and improvements within the plant, including a new and revised HACCP plan, new cleaning and sanitation procedures, advanced testing requirements, structural modifications (new roof, floors reconditioned), and new equipment (b)(4) (b)(4)

A new HACCP plan has been developed for the firm's operations, see EXHIBIT # 3. According to Dr. Hall, extensive work has gone into the revision of the HACCP plan, which was developed to cover all products manufactured at this plant. He stated that the bulk of the HACCP plan involves the validation of the new roaster, and the documentation of HACCP training for the firm's employees. The validation of the (b)(4) roaster was conducted by ConAgra's microbiology staff, see page 242 of EXHIBIT # 3. The study revealed that the lethality of roasting can be maximized by (b)(4)

(b)(4) as opposed to the traditional roasting with a (b)(4) (b)(4)

The firm has established new cleaning procedures for all areas of the plant. See EXHIBIT #5 for a copy of the firm's Sanitation/Cleaning Protocol. When I received the firm's written procedures for cleaning, Mr. Ehret reminded me that the firm would probably continue to improve and modify their procedures over time, so the copy of the firm's protocol that I received was subject to change. I explained that I understood, but that I wanted to include the current cleaning and sanitizing procedures with my report to emphasize the firm's efforts for improvement and guidance provided to the employees. The new cleaning procedures performed by the firm are discussed in the following section of this report (Cleaning/Sanitation Procedures).

Mr. Ehret informed me that they now have a new sanitation policy for employees and visitors where anyone entering the plant must have steel-toe shoes that remain at the plant. He said that the employees all have "captive shoes" which are steel-toed shoes purchased by ConAgra for the employees to wear while at the firm, but once the employee leaves the firm the shoes are removed and left in lockers, offices, etc. For visitors that do not have the required set of shoes, a set of steel-toed, rubber slip-on covers that go over regular street shoes are provided. Before entering the

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production area, all shoes and shoe covers are sprayed with (b)(4) sanitizer. A 2 gallon spray pump containing the sanitizer is positioned at each plant entrance for this purpose. Mr. Elrefaie stated that they are trying to come up with a shoe dipping station that would be easily accessible and efficient, but for now they feel that using the spray pump, although a lot of sanitizer is wasted, is providing them with the preventive steps their plant needs. Mr. Ehret stated that they are planning on creating a Visitor Supply Center, which would be located near the plant entrance. This area would have a supply of hair nets, beard covers, ear plugs, shoe covers, etc, that could be a convenient and comfortable area to put on proper attire before entering the plant. During the inspection, many construction crews and maintenance workers, not affiliated with ConAgra, were observed working in the firm. I asked if they had any problems getting the outside workers to follow their sanitation procedures. Mr. Elrefaie said that before the workers were hired they were required to attend a safety and sanitation training session put on by ConAgra. He said that most of the contractors were very reliable, but some had to be reminded on occasion about using specific plant entrances and wearing hard-hats correctly.

Since the previous inspection, the firm has (b)(4) the raw peanut storage and pre-cleaning areas to reduce future risk problems by segregating this area from the rest of the plant. Previously (b)(4) between the receiving dock area and other areas within the plant such as the roasting area. In addition, the (b)(4) of the raw peanut process flow have a (b)(4). Only authorized personnel are allowed in this section and upon entering the raw area employees are required to wear (b)(4) suits or smocks and shoe covers. When entering the raw peanut storage room, pre-cleaning room, or COP wet wash room for this section, visitors are required to wear white slip-on shoe covers. When exiting the raw product area going into other areas of the plant, (b)(4) suits/smocks and shoe covers are removed and discarded. Additionally, this area has a restroom dedicated for personnel working in the raw product areas.

The firm now uses (b)(4) dedicated to specific areas instead of (b)(4) in the plant. For instance, a (b)(4) is used in the pre-clean area to minimize the amount of peanut dust on the equipment and throughout the room. Also, a (b)(4) is used in the roaster room to remove floor waste.

The firm now has COP "clean out of place" wet wash area dedicated to the raw peanut storage and pre-cleaning areas. Equipment that can be dismantled and removed is taken to that area to be cleaned and sanitized. Equipment and tools such as star-wheels, indexers, screws, screens, buckets, tools, cappers, and filters are taken off of the lines and taken for cleaning in this area.

Throughout most of the plant, the old top layers of the concrete floors have been scraped off, and a (b)(4) has been applied. Management stated that the new floors are easily cleaned and sanitized as they are smooth and not pitted with worn spots and holes. The receiving dock area and walk-ways located between production rooms are the only areas that still have the old concrete floors. Mr. Elrefaie stated that they had plans to refinish all of the floors, but they had concentrated

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on the areas along the process flow first. In addition, new and improved lights have been installed throughout the plant for better visibility.

A new HVA (heating ventilation air conditioning) system, equipped with (b)(4) filters, has been installed. The raw peanut storage and pre-cleaning areas have been set up with a (b)(4) system. The remainder of the plant is set up with (b)(4) system starting at the south end of the building and flowing to the north end of the building. This allows a "finished to raw" product (b)(4) starting in the production/filling room, flowing back down the process line, and then out of the plant, not vice versa. The (b)(4) system runs through a (b)(4) and set of (b)(4) filters.

The firm purchased new tools and utensils, such as trash cans, brooms, mops, and squeegees, that are color coded to segregate and identify equipment or utensils dedicated for certain areas. For instance, red items are dedicated to the raw peanut portion (raw receiving, raw bins, pre-clean, and roaster entrance area), green items are dedicated to the process flow after the roaster (Blanching room, Milling area, Tank room, and Production/filling area), and blue items are used in the warehouse. Personnel assigned to these areas also have bump caps with corresponding colors (red in red). Brushes are also color coded for each specific area of use. For example, Red bristles are used on raw product contact surfaces, white bristles are used on food contact surfaces, green bristles are used on equipment exteriors, blue bristles are used on floors and walls, and black bristles are used on floor drains. These brushes are sanitized after each use. Fork lift wheels have all been replaced with smooth, white wheels that can be cleaned and sanitized easily. The old COP wet wash room is now referred to as the Scrubber/Wash Room and it is strictly used for the cleaning of fork lift wheels, pallet jacks, and floor scrubbers.

Mr. Ehret stated that a new roof has been installed over the plant. He said that the warehouse is a fairly new addition to the firm, thus a new roof was not needed in that area. Management stated that the interior portion of the roof was also replaced, and it now consists of a layer of (b)(4) (b)(4) Mr. Ehret stated that this was to prevent any condensation forming and dripping onto the production line.

Since the previous inspection, the firm has raised equipment, machinery, and buckets in the blanching and color sort room 18" off of the floor. Mr. Ehret said that this was done so that the floors and equipment could be cleaned easily. The firm was in the process of installing another (b)(4) during the inspection.

The section of the building that previously housed the old roaster has been converted into several sectioned-off rooms consisting of the Instrument/Roaster Control Room, Fines Roaster Room (not in operations), mechanical equipment room for parts, and the COP room for the (b)(4) new room was added onto the east wall for the (b)(4) (b)(4) During the week of August 6th, the firm experienced some leaks in the (b)(4) room on the south wall (exit area of the roaster), where the SW corner of the new addition joined the original section of the plant. Mr. Ehret said that the

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leak did not appear to have come from a leak in the roof, but rather a leak on the wall where the (b)(4) (b)(4) room is connected to the old building. This structural problem is also discussed in the "Analytical Test Results" section of this report. Mr. Ehret said that when source of the leak was identified, they decided to apply an (b)(4) to the exterior wall and a portion of the roof for (b)(4) (b)(4) room. He said that this (b)(4) is similar to the (b)(4). This (b)(4) was applied to the wall and onto several feet of the roof where the roof and wall was joined. After the (b)(4) was applied, the firm had the (b)(4) Fire Department to come to their plant and spray huge bursts of water onto the exterior portion of the wall so that any additional leaks could be detected. Mr. Ehret said that the Fire Dept. came out and sprayed the building with water several times within the past few weeks, and no leaks were observed.

The production lines are now covered with (b)(4) prior to the filling stations, and after the fillers the lines are covered with a stainless steel cover. Previously, some areas over empty jars along the lines were uncovered.

The warehouse now has increased in-house storage capacity. Jars are immediately taken off of the trucks upon arrival. The warehouse temperature is kept around (b)(4) F with low humidity. Mr. Ehret stated that the warehouse was emptied and completely cleaned and sanitized. All products remaining in the warehouse after the previous inspection has been destroyed at landfills located (b)(4) and (b)(4). See EXHIBIT # 6 for copies of the Certificate of Destruction for the old product.

During the previous inspection, it was noted that the firm sold their waste material for animal feed. Currently, the firm's waste is taken for disposal at a landfill.

Cleaning and sanitizing supplies

According to Mr. Kimbrell, the plant has changed the supplier of their cleaning and sanitizing agents. The following supplies are used by the firm:

(b)(4) produced (b)(4) Alcohol wipes); used as a hand sanitizer and to wipe down food contact surfaces. (This is the product used when the cleaning protocol refers to (b)(4)

(b)(4) produced by (b)(4) Blend); used on utensils, equipment, floors, and walls as the final sanitizer. This product is also referred to as (b)(4) (b)(4) in the Cleaning Protocol.

Stainless Steel Polish (Aerosol Stainless Steel Compound); used to polish the outside of tanks.

The following cleaning and sanitizing agents are produced by (b)(4)

(b)(4) Sanitizer, Deodorizer, Disinfectant (b)(4) Sanitizer); applied to food contact surfaces, utensils, equipment, floors, and walls. This product is also used to sanitize employee/visitor shoes prior to entering the plant.

(b)(4) liquid (b)(4) Cleaner); used in the large cleaning tanks located in the COP wet wash rooms for cleaning COP equipment and utensils, including screens, gaskets, housing covers, sliders/donuts.

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(b)(4) Surface Barrier/Release Agent and Cleaning Aid); used to polish non food contact surfaces.

(b)(4) foam cleaner); used to clean grates and traps from floor drains, trash cans, and walls and floors of wash rooms.

(b)(4) granular floor treatment compound); used on raw peanut receiving area floors, employee entrance at back of plant, and walk-ways between processing areas.

(b)(4) foam cleaner for (b)(4) used with (b)(4) to clean the interior of the roaster, including the roaster belt, heating and cooling sections, exterior vibratory and bucket elevator.

(b)(4) Liquid General Purpose Cleaner); used to clean CIP (clean in place) equipment, including (b)(4) hoppers, color sorters, augers; used in the dispensing unit on the floor scrubbers; and used to clean fork lift wheels.

See EXHIBIT # 7 for the product description and specifications for the above cleaners and sanitizers.

Cleaning/Sanitation Procedures

Management stated that the firm has undergone a complete detailed cleaning and sanitizing since March. He said that all of the equipment that could be dismantled was taken apart and sanitized. Formulation tanks and pipes that could not be removed were flushed with (b)(4) Mr. Ehret said that they had rented a large boiler and heated the (b)(4) and then they flushed this through the equipment which melted any remaining product and acted as a kill step. Mr. Ehret stated that the entire plant (floors, walls, ceilings and equipment) has been cleaned and sanitized by 3 steps: first wipe down with (b)(4) second sprayed with (b)(4) and third sprayed with (b)(4) and allowed to air dry. According to Mr. Elrefaie, this is the new standard procedure for cleaning equipment, floors, walls, and utensils in the plant.

The firm has purchased a new (b)(4) Floor Scrubber to clean the floors in the raw receiving area on a (b)(4) basis. Once the floors have been cleaned by the scrubber with a solution of (b)(4) granules) are broadcast in the raw peanut receiving areas, employee entrance in back of the plant, and other walk-ways located in the plant. Other processing areas are cleaned (b)(4) with a mop bucket containing a general purpose cleaner (b)(4) The raw portion of the production flow has dedicated mop buckets, which are used only in this area. Grates and traps on floor drains are cleaned (b)(4) with (b)(4) rinsed with water, then saturated with (b)(4) solution and allowed to dry.

Equipment in the bulk peanut receiving area such as augers, storage bins, frames and buckets are blown down and then vacuumed with a large canister type, rolling vacuum that is dedicated to this specific area. All areas containing meal and dust are vacuumed, and then wiped down with sanitizer

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wipes on (b)(4) basis. Floors in this area are cleaned with the walk behind scrubber. The vacuum used in this area is dedicated and only used in the raw peanut section of the plant.

The old COP wet wash room is now referred to as the Scrubber/Wash Room and it is strictly used for the cleaning of fork lift wheels and floor scrubbers. Fork lift wheels and wheel wells are cleaned and sanitized (b)(4) and the floor scrubber brushes are cleaned (b)(4) with an application of (b)(4). Once the (b)(4) is rinsed off, the wheels and brushes are saturated with (b)(4) solution and allowed to dry.

The (b)(4) is cleaned (b)(4) that sprays (b)(4) cleaner (b)(4) onto the roaster belt as it is rotated around the frame. The heating and cooling transfer sections, as well as the roaster exterior vibratory and bucket elevator are also sprayed with the foam (b)(4) but Mr. Kimbrell said that they were having one made to help with the rinsing. Once the interior of the roaster is rinsed, (b)(4) (b)(4) sanitizer is sprayed onto all equipment surfaces and allowed to dry.

In-house testing procedures

According to Mr. Kimbrell, all environmental swabs and finished product samples collected are now shipped to (b)(4) (b)(4) for analysis of (b)(4) (b)(4). No microbiological testing is conducted at the firm's lab. See EXHIBIT # 8 for a copy of the firm's Microbiological Sampling and Testing procedure. Dr. Warren stated that the testing procedures for finished product and environmental swabs were still under review and the procedure would probably be modified as operations at the plant expand. He said that they have been collecting an unusually large amount of swabs in order to verify the effectiveness of their cleaning and sanitation, as well as making sure that the plant was free from *Salmonella* before they began operations. Dr. Warren said that their current written procedures require the collection of (b)(4) swabs each (b)(4) from various locations or "zone sites". According to the firm's written procedures: *Zone 1 sites* includes product contact surfaces (highest risk sites for product contamination); *Zone 2 sites* includes only non-product surfaces at close proximity of the product; *Zone 3 sites* includes non-product contact surfaces at the production areas of the facility or equipment (i.e. forklifts); and *Zone 4 sites* includes non-product contact surfaces at the non-production areas of the facility and equipment (lowest risk sites for product contamination). Dr. Warren explained that the current procedures state that they collect (b)(4) swabs from zone (b)(4) swabs from zone (b)(4) swabs from zones (b)(4). I explained to management, that on the first day of the inspection, Mr. Kimbrell stated that the firm was collecting (b)(4) swab samples per zone and then (b)(4) random samples throughout the plant each (b)(4). I told management that I had received conflicting information for the new procedure for the collection of environmental swab samples, and that the employees permanently positioned at the firm that would be routinely collecting these samples should be clear on the number and location of the swab sample collections. Dr. Warren commented that one of his top priorities was to work with Mr. Kimbrell and establish a clear set of procedures to identify sampling sites and testing requirements. Mr. Elrefaie stated that in addition to the routine

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swabbing, the firm is also required to collect swabs after building renovations, changes in equipment, corrective action verification, and investigative swabbing for a root-cause analysis.

(b)(4) air sampling for (b)(4) will also be conducted by exposing Petri film strips to air at specific sites in the plant. According to Mr. Kimbrell this procedure is also being finalized by Dr. Warren.

Finished product sampling includes the collection of (b)(4) finished product jars (b)(4) (b)(4) composites are made by taking (b)(4) of product from (b)(4) Mr. Kimbrell reported that all finished product is on hold until the test results are received from (b)(4) which is usually (b)(4) days for finished product and (b)(4) days for swabs. He stated that the finished product is on an in-house temporary hold for a minimum of (b)(4) days.

Other finished product tests include (b)(4) (b)(4) roasted peanuts and finished product (b)(4) (b)(4) is checked on crunchy peanut butter products.

Analytical Test Results

According to management, approximately 2 weeks prior to the start of operations on 8/6/07, they collected numerous environmental swabs throughout the plant. EXHIBIT # 9 contains the description of the sites swabbed and the analytical results received from (b)(4) it should be noted that (b)(4) of the swabs were found to be positive for (b)(4) see pages 50, 60, and 86 of EXHIBIT # 9. Each location was identified by the firm (b)(4) and corrective actions were conducted and documented for each site. Pages 136 through 152 of EXHIBIT #9 are analytical results for a trial production run performed by the firm prior to the start of operations. These results were negative.

EXHIBIT # 10 contains the results for the environmental swabs collected by the firm during the first week of operations (b)(4) collected on 8/9/07 from (b)(4) the (b)(4) was positive for (b)(4) see page 7 of EXHIBIT # 10. Mr. Ehret said that they discovered that this particular leak was coming from the roof where the new portion of the plant was added onto the old building. He stated that they were not running the (b)(4) on this date; however, they decided to shut down all operations and conduct a thorough cleaning and sanitizing. Mr. Ehret said that during this down-time they had an (b)(4) applied to the exterior wall and the roof over the (b)(4) Mr. Elrefaie reported that they then collected swabs from this area for (b)(4) consecutive days and the swab results were negative. [Sample # 434893, collected on 8/22/07, consisted of 18 environmental swabs collected in and around this area.]

Mr. Ehret stated that the test results for their finished products have all been negative for (b)(4) See EXHIBIT # 11 for a copy of the firm's Daily Production Schedule with corresponding analytical results from (b)(4) for product manufactured at this site from 8/6/07 to 8/17/07.

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Processing Flow/Equipment

During the inspection the firm was producing 18 oz. and 40 oz. Peter Pan Creamy and 40 oz. Peter Pan Crunchy Peanut Butter. There have been several changes in operations since the last FDA inspection in February of 2007.

Raw, shelled peanuts are shipped to the firm in dedicated bulk tankers owned by (b)(4). The raw peanuts are pneumatically unloaded from the tankers and transferred into bulk bins located inside the facility for temporary holding. The bulk bins are split into quarters amounting to (b)(4) separate bins, each with the capacity of (b)(4) lbs. Each bulk bin has a ticket on the side identifying the bin #, lot # of raw peanuts (first 2 #'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, producing a co-mingled lot. This allows the firm the ability to trace a specific lot or supplier from a production date.

Each lot of raw peanuts delivered to the firm is accompanied by the USDA Grade and Inspection Certificate and Aflatoxin analysis report. The raw nuts are visually inspected by the firm's QC department, and in-house samples are collected for aflatoxin (max. of (b)(4) for sub samples) and (b)(4) content (usually about (b)(4)). The firm does not have a minimum or maximum limit for (b)(4) however, the higher the (b)(4) the longer the peanuts would have to be (b)(4).

From the bulk holding bins, the raw peanuts are gravity fed onto a horizontal conveyor which carries the raw nuts to the vertical bucket conveyor that feeds the nuts onto (b)(4) (b)(4) that goes through the concrete block wall separating 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) machine, which mechanically removes large foreign objects through (b)(4). Sticks and other large foreign objects vibrate across the top screen of the equipment and are separated from the peanuts which fall through the top screen onto a second screen. The raw peanuts are transferred over a (b)(4) and then carried to a bucket conveyor which leads into the holding bin supplying raw peanuts to the (b)(4) Separators), which removes smaller stones and other foreign objects. Small peanut pieces and broken peanut kernels, etc. that fall through the second screen are also conveyed to the (b)(4) Separators. All sizes of peanuts from the (b)(4) separator are combined and enter a horizontal bucket conveyor which is discharged into the (b)(4) separator. From this (b)(4) the peanuts are conveyed to a (b)(4) conveyor which empties into (b)(4) that feeds the cleaned peanuts onto an (b)(4) which transfers the peanuts into a holding bin located inside the roasting room, where peanuts are gravity fed onto the (b)(4) (b)(4).

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According to the firm, the (b)(4) Roaster is (b)(4) long and (b)(4) wide. A new room was built onto the east wall of the old plant, specifically for the roaster. This roaster has (b)(4) heating zones and (b)(4) cooling zones, whereas the old roaster had (b)(4) heating zones and (b)(4) cooling zones. The dwell time for peanuts remaining in the roaster heating zones is a minimum of (b)(4) minutes with a bed depth (b)(4). Temperature of roaster zones: zones (b)(4) °F, for a minimum of (b)(4) minutes; zones (b)(4) °F, for a minimum of (b)(4) minutes; and zones (b)(4) °F for a minimum of (b)(4) minutes. The dwell time is monitored by belt speed, which is measured in Hertz (feet/minute). When product enters the cooling zones, this stops the cooking process so the product is not overcooked. Roasted peanuts fall off the roaster belt at approximately (b)(4) onto the vibratory belt. The peanuts are probed at the exit of the roaster for temperature. The times and temperatures within the roaster are monitored by a computer located in the roaster room at the roaster exit. Mr. Ehret stated that the time and temperatures of the roaster for any production date could be generated and reviewed.

The roasted peanuts are transferred from the roaster onto a (b)(4) conveyor that moves the peanuts to a (b)(4) conveyor, where the peanuts are discharged to the upstairs holding bins, each having (b)(4) capacity. From the holding bins, roasted peanuts are feed into the (b)(4) (b)(4) where the nuts are conveyed through the (b)(4) (b)(4) the peanuts and aspirated from the process flow. The nuts are then conveyed (b)(4) elevator and feed into the (b)(4) system (b)(4) (b)(4) which rejects off-colored nuts, foreign material, etc. from the product flow. Blanched peanuts passing through the color sorters are transferred to a screw auger conveyor that pneumatically transfers the peanuts to the finished nut holding bins on the mezzanine (b)(4) in the West bin and (b)(4) in the East bin). Mr. Ehret said that the holding bins that were open-topped bins during the last inspection are now covered as an added level of precaution. This was verified on 8/20/07.

At this point, roasted and cleaned peanuts in the holding bins are passed over a set of (b)(4) (b)(4) before being gravity fed into (b)(4) that empties into the (b)(4) the primary grinding mills. A change in the operations occurs at this point, where roasted peanuts (b)(4) (b)(4) transfer system has been installed to add (b)(4) on an "as needed basis" into the process flow via an auger. During this primary grind, the (b)(4) (b)(4) To make crunchy peanut butter, roasted peanuts are diverted in the product flow to the (b)(4) mill from the finished nut holding bins, where the nuts are chopped for a specific size. Chopped peanuts then pass through (b)(4) screens to grade the nuts for the correct size. Chopped 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 products.] The ground peanuts and (b)(4) are then transferred to the (b)(4) Mills, the (b)(4) grinding, where the (b)(4) is added to the product. The firm has applied (b)(4) (b)(4) where the (b)(4) mills take the place (b)(4) which have been removed. Since the previous inspection, the firm has removed (b)(4) leaving them with only (b)(4) formulation tanks. Mr. Ehret stated that they removed the tanks to eliminate surge capacity and the amount of time the peanut butter would sit in the tanks. During the (b)(4) grind in the (b)(4) Mill,

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the product is ground to achieve a creamy texture. At this stage, the friction from the mixing of the ingredients causes the temperature of the product to increase to (b)(4) F.

[It should be noted that the firm is equipped with a separate system for products containing (b)(4) such as the Reduced Fat or Smart Choice products. The addition of ingredients and the mixing of these products are conducted in the (b)(4) Mixing room. This area is equipped with hoppers and a (b)(4) mill, which blends the ingredients. This area has been thoroughly cleaned and sanitized, but the system is not scheduled for production until November of 2007.]

Next, the peanut butter is pumped to the (b)(4) tank for (b)(4). During the (b)(4) process the temperature of the product decreases to about (b)(4) F. Next, the product is transferred through a (b)(4) to the (b)(4) cooling system. At this time, the peanut butter passes through votators or heat exchangers to cool down the product. The cool down temperature after passing through the votators for creamy and crunchy peanut butter is within (b)(4) F before passing to the filling machines. The cooling media in the votators is (b)(4) for all products, with the exception of the smart choice/reduced fat products which are cooled by (b)(4) in the votators.

Creamy peanut butter is conveyed from the votators to the fillers. For crunchy peanut butter, chopped peanuts temporarily stored in the holding bin are discharged to the crunchy weigh feeder and added to the peanut butter flow at the mixing tanks prior to filling.

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 feed 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 lines (b)(4) and creamy peanut butter products can be run on lines (b)(4). (b)(4) is used to fill 12 and 18 oz. jars; (b)(4) is used to fill 22, 28 and 40 oz. jars; (b)(4) is used to fill 12, 18, 22, 28, and 56 oz. jars; and (b)(4) is used to fill 6 lb. cans of creamy and 18 and 28 oz. jars of smart choice/reduced fat products.

Empty jars are inverted and blown out with filtered air to remove foreign materials. The jars are then conveyed to the fillers. Peanut butter is mechanically filled at about (b)(4) F on rotating fillers which enter the jars and fill from the bottom to the top. The filled jars exit the fillers and are conveyed through a metal detector, and then (b)(4) injected into the head space of each jar prior to the plastic screw cap being applied to each jar. A foil seal is applied to each jar by (b)(4) Induction Sealer, 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 then passed through the label applicator and the ink jet printer for the manufacturing code. Labeled jars are then mechanically packaged into cardboard trays that are shrink wrapped in clear plastic and case coded. Finished products are stored in the firm's warehouse, until ready for distribution. The warehouse is also used for storage of packaging materials (jars, caps, cases, etc.).

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MANUFACTURING CODES

The lot codes for each product are inked in black dot-matrix on the jar lids of each product. The first 4 numbers of each lot code represent the Sylvester plant. Previously, the plant number was "2111", whereas the new plant number is "5273". The remainder of the lot coding system is unchanged.

For example: "52737232000805A"

5273 = is the Sylvester plant number

7 = is the year 2007

232 = 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)

The firm's "Use by Date" is 18 months from the production date. The code applied to the product manufactured at (b)(4) is the same as above with the exception of the plant number being "5276".

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**Observations listed on form FDA 483**

OBSERVATION 1

Effective measures are not being taken to exclude pests from the processing areas and protect against the contamination of food on the premises by pests.

Specifically, a roll type door located in the raw peanut receiving area had a 1" opening along the bottom of the door. In addition, one fly was observed in the roaster room on 8/20/07. One fly was observed in the packing line area on 8/20/07. One fly was observed in the raw peanut receiving area on 8/20/07 and 8/21/07.

Reference: 21 CFR 110.35(c)

Discussion with Management:

During the walk-through inspection on 8/20/07, I observed a metal roll-type door located in the raw peanut receiving dock area with approximately 1" opening along the bottom of the door. This door led to the exterior of the plant and daylight could be seen through the opening. This objectionable condition was pointed out to management and I explained that this could be where the flies I had observed had entered into the plant. On 8/22/07, I observed that this door had been sealed off with

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thick plastic, and no openings were visible. Mr. Elrefaie informed me that they were planning on replacing all of the roll-type doors in this area, but in the meantime they would keep the door sealed with plastic so that there would be no exposures to the outside of the plant.

OBSERVATION 2

Failure to store cleaned and sanitized portable equipment in a location and manner which protects food-contact surfaces from contamination.

Specifically, dismantled equipment used on the filling/production line (not in use) was stored on a thin piece of cardboard on the floor of packaging area. This equipment was tagged as "cleaned."

Reference: 21 CFR 110.35(e)

Discussion with Management:

This deficiency was pointed out to management on 8/21/07 during the walk-through inspection. I asked if this was how they routinely stored cleaned and sanitized equipment prior to placing an item back on the production line. Mr. Kimbrell assured me that this was not their routine procedure, and he would make sure that the equipment was properly cleaned and sanitized and stored correctly. I verified that the equipment had been tagged as "unclean" on 8/22/07.

OBSERVATION 3

Failure to provide safety-type lighting fixtures suspended over exposed food.

Specifically, a light fixture missing the protective covering was observed on the 2nd floor area, directly in front of the ingredient storage room.

Reference: 21 CFR 110.20(b)(5)

Discussion with Management:

During a walk-through inspection on 8/22/07, this objectionable condition was brought to management's attention. Mr. Elrefaie immediately notified employees responsible for this area, and instructed them to correct the deficiency. He said that he would use this discrepancy to illustrate how supervisors and team leaders should consistently inspect their areas for problems. The deficiency was corrected immediately.

SAMPLES COLLECTED

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Shortly after the start of the inspection on 8/20/07, I was joined by Chauncey A. Stephens and William (Bill) K. DuCloux, Microbiologist from the Southeast Regional Lab. The analysts assisted with the collection of finished product, raw peanuts, and environmental swab 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. The firm's swab samples were collected by Dr. Hall and Dr. Warren. Also, the firm collected a duplicate sample of each finished product collected by FDA. 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.

On 8/20/07:

Sample #434885 consisted of 15/18 oz. jars of Peter Pan Creamy Peanut Butter, lot code "5273723200---- - BEST BY FEB102009";

Sample # 434886 consisted of 15/40 oz. jars of Peter Pan Creamy Peanut Butter, lot code: "5273723200--- --- BEST BY FEB102009".

On 8/21/07:

Sample #434887 consisted of 25 aseptically collected environmental swabs of various areas and equipment throughout the plant;

Sample # 434889 consisted of 25 aseptically collected environmental swabs of various areas and equipment throughout the plant;

Sample # 434890 consisted of 25 aseptically collected environmental swabs of various areas and equipment throughout the plant;

Sample # 434891 consisted of 29 aseptically collected environmental swabs of various areas and equipment throughout the plant;

Sample # 434892 consisted of 15/ approximately 300g subs of raw peanuts collected from the raw peanut storage bin (b)(4)

Sample # 434894 consisted of 10/40 oz. jars of Peter Pan Crunchy Peanut Butter, lot code "5273723300----- BEST BY FEB112009".

On 8/22/07:

Sample # 434893 consisted of 18 aseptically collected environmental swabs of various areas and equipment throughout the plant;

Sample #434895 consisted of 15/40 oz. jars of Peter Pan Creamy Peanut Butter, lot code "5273723400----- BEST BY FEB122009".

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CLOSING DISCUSSION

Mr. Earl Ehret, Joseph Elrefaie, Joey Kimbrell, and Dr. Benjamin Warren were present during the closing discussion. The FDA-484 was issued to Mr. Ehret. The FDA-483 was also issued to Mr. Ehret and the deficiencies were discussed. Each item was discussed during the walk-through of the plant, thus management was not only aware of the objectionable conditions, but corrections had already been made. I informed them that I had verified the corrections to the items noted and that I would include this in my report.

It should be noted, that at approximately 1:30 a.m. on 8/23/07, the plant received an extremely heavy rainfall. When I arrived at the firm at 10:00 a.m. on 8/23/07 for the closing discussion, I asked Mr. Ehret if they had observed any leaks in the plant. He told me that anytime it rained when he was away from the plant, he would make a point of coming back to the firm and completing a walk-through inspection for leaks or other problems. He stated that he had arrived at the plant earlier that morning and they had found (b)(4) in packaging and (b)(4) (the warehouse) after the rain. A walk-through inspection was conducted and I observed that the leaks were not within a close vicinity to food contact surfaces or product and corrective actions were already in progress. Mr. Ehret said that they had just installed gutters along the side of the building and that the leak in the packaging area was caused from a heavy burst of rainfall coming out of a gutter that was not directed away from the side of the building. He said that they had examined the exterior of the plant at this section, and the excessive amount of water coming off of the roof was flooding the area around the point where water was leaking or bubbling into the packaging room wall. Mr. Ehret stated that they were already in the process of having gutter drains placed on the outside of the building so that water would be directed out and away from the building. Additionally, they have already caulked the outside of the wall. The area around the leak in the plant was sanitized and then swab samples were collected. Mr. Elrefaie stated that they would swab this area for (b)(4) consecutive days to verify that their corrective actions were adequate. The other (b)(4)s, located in the warehouse, were not within close proximity to product or packaging supplies. One drip was observed at the truck-dock connecting pad of dock door #1, one drip observed near a wall bracket for a light beside a dock door, and the other drip was located at the roof/overhang juncture near a door. Mr. Elrefaie informed me that although these leaks were away from the production areas, they had already saturated all of the areas with (b)(4) Before the closing discussion was completed, a roofer had arrived at the plant to repair the roof in the warehouse. I told Mr. Ehret that I would like to walk through the plant once more to verify that no other leaks had occurred within the facility. No other leaks were observed in the plant.

I explained to management that their cooperation during the inspection was appreciated. Mr. Ehret stated that they wanted to be completely open with FDA because they had nothing to hide and that a working relationship was one of their objectives. He said that they would be glad to have anyone from the FDA to come to their plant for a visit because they were extremely proud of their improvements and accomplishments.

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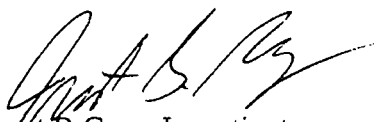
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EXHIBITS

- EXHIBIT # 1: Copy a Bill of Lading #004633779M, Shipping Manifest, and Packing List/Loading Sheet, dated 8/21/07, for the shipment of (b)(4) cases of 40 oz. Peter Pan Creamy Peanut Butter Organizational chart for ConAgra Foods; 3 pages
- EXHIBIT # 2: Product labels; 3 pages
- EXHIBIT # 3: Firm's revised HACCP plan; 379 pages
- EXHIBIT # 4: ConAgra Cover Letter accompanying each record received; 2 pages
- EXHIBIT # 5: Copy of the firm's Sanitation/Cleaning Protocol; 44 pages
- EXHIBIT # 6: Copies of the Certificate of Destruction for the product recall issued during previous EI; 153 pages
- EXHIBIT # 7: Description and specifications for the cleaners and sanitizers used in the plant; 12 pages
- EXHIBIT # 8: Firm's Microbiological Sampling and Testing procedure; 8 pages
- EXHIBIT # 9: Swab Sample Results and collected by the firm prior to start-up of operations; 152pages
- EXHIBIT # 10: Swab Sample Results collected during the first week of operations; 88 pages
- EXHIBIT # 11: Firm's finished product test results since the start of their operations on 8/6/07; 22 pages

ATTACHMENTS

- FDA-482, Notice of Inspection; 2 Forms issued on 8/20/07
- FDA-484, Receipt for Samples
- FDA-483, Inspectional Observations
- Collection Reports for Samples collected during EI


Janet B Gray, Investigator