

Establishment Inspection Report

Pepsi Bottling Group, LLC
Orlando, FL 32809-6226

FEI: 1014171
EI Start: 08.04/2009
EI End: 08/11/2009

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SUMMARY (RLM)

Comprehensive inspection of this manufacturer and distributor of bottled, canned, and bag in box carbonated flavored soft drinks, flavored tea beverages, fruit flavored beverages, and bottled water beverages was initiated per FLA-DO 3rd Qtr. FY'09 Work Plan (FACTS #1073460 / Operations ID 4296803). In addition, a follow-up to CC #93105 was conducted for Diet Pepsi. Coverage was pursuant to C.P. 7303.803 Domestic Food Safety Program (PACs 03R803, 03R801, 09803). Firm's adherence to GMP was verified by inspection of the plant's manufacturing/warehousing facilities and review of hazard analysis and the firm's version of a HACCP plan for the manufacture of bottled, canned, and bag in box carbonated flavored soft drinks, flavored tea beverages, fruit flavored beverages, and bottled water beverages. It covered the firm's receiving/storage of raw materials and primary and secondary packaging materials, monitoring records, sanitation records, equipment calibration/preventive maintenance, training, consumer complaints, labeling and use/storage of chemicals.

Previous inspection revealed a FY-09 FDACS State Contract Inspection conducted, on April 21, 2009 and classified as VAI. During the FDACS State Contract Inspection, objectionable conditions were noted to include a gap under a door. This deficiency was reported to Lisa Yates, Manager who responded that corrections would be made. FDACS were also present at the start of our inspection.

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Current inspectional observations revealed no objectionable conditions, noted by FDA inspectors, warranting the issuance of FDA 483, Inspectional Observations and the inspection was classified as NAI. Follow-up to CC# 93105 revealed, as disclosed by the firm's Plant Manager, QA Manager, and HQ Quality Senior Field Representative for PBG International Affairs, that the firm had initiated a PBG internal investigation, efforts were ongoing, and thus far, had not uncovered a root cause and as a result, a corrective action request was not generated internally at the plant level or headquarters level. There were no samples collected, however a field exam, and label review was conducted, **(Exhibit #4, 12 pages)**. A reconciliation exam was also conducted for 32 forty-eight gallon drums of [REDACTED] Flavoring, [REDACTED] **(Attachment #11, 1 page)**. (b)(4)

Refusals were encountered only when requesting copies of documents however, the firm did allow viewing of all documents allegedly available at the firm. Copies of documents were refused by Tanya Peacock, HQ Quality Senior Field Representative for PBG International Affairs on behalf of Plant Manager Kevin Sullivan on reported authority of Corporate Legal Counsel, Dave Patrick and VP of World Wide Quality, Gina McElgunn.

After consultation with FDA district management, I communicated their concerns to the Plant Manager, Kevin Sullivan; QA Manager, Duen Pagon; and HQ Quality Senior Field Representative for PBG International Affairs, Tanya Peacock who took notes regarding voiced FDA concerns and indicated that they would certainly take FDA district management concerns into consideration and share them with their superiors.

FDA concerns are as follows: there should be additional quality procedure checks and conformance to specification checks (CTS) in place at the receiving stage of primary packaging materials, particularly the can line, to assure that no foreign objects are in the cans prior to processing and filling; that there were no documented quality assurance tests or studies performed to assure or validate that the firm's reported combined mechanical processes and experiential observations were sufficient enough to ensure that a can with a foreign object would be rejected prior to final secondary packaging; that the de-ionized air rinser has not been proven to wash out a foreign object of any size, other than particulate matter, that clings to the insides of bottles and cans as noted on the de-ionized air rinser specification; that there were no quality assurance tests or studies done to support the firm's experiential claim that a foreign object in a can would result in the can foaming while filling, causing a premature shut off of the ball filler valve, which would always result in an under-filled can, always causing the can to be ejected by the [REDACTED] device and prevent final secondary packaging from occurring. (b)(4)

Copies of the "ALERT" and "FIRST" food defense awareness initiatives were provided to and discussed with the Plant Manager, Kevin Sullivan and the Quality Control Manager, Duen Pagon.

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ADMINISTRATIVE DATA (RLM)

Inspected firm: Pepsi Bottling Group, LLC
Location: 1700 Directors Row
Orlando, FL 32809-6226
Phone: 407-826-5989
FAX: 407-826-5979
Mailing address: 1700 Directors Row
Orlando, FL 32809-6226

Dates of inspection: 8/4/2009, 8/5/2009, 8/7/2009, 8/10/2009, 8/11/2009
Days in the facility: 5
Participants: Randall L. Morris, Investigator, (8/4-5/2009, 8/7/2009, 8/10-11/2009)
Deborah A. Racioppi (DAR), Investigator, (8/4-5/2009, 8/7/2009)
Lindsay R. Mundy (LRM), Investigator, (8/10-11/2009)

On 8/04/09, Investigator Debbie A. Racioppi and I presented credentials, explained the purpose of inspection, and issued the FDA 482, Notice of Inspection, to the Plant Manager, Kevin Sullivan. A second FDA 482, Notice of Inspection was issued to the Plant Manager, Kevin Sullivan on 8/10/09 by me and Investigator Lindsay R. Mundy at the time of her assignment to the inspection.

This EIR was written by me, Investigators Racioppi, and Mundy. Investigator Racioppi and I inspected the firm on 8/4-8/5/09 and 8/7/09. Investigator Mundy and I inspected the firm on 8/10-11/09.

Investigator Racioppi and I were accompanied, during our inspectional walk through of the firm's facilities on 8/4/09 by the Plant Manager, Kevin Sullivan; Quality Control Manager, Duen Pagon; and the Vice President, Manufacturing Southeast Business Unit, Ed Ballina, (**Exhibit #3, 1 page**). On 8/5/09 through 8/11/09, the following key management staff and visiting PBG HQ Quality staff were present during the inspectional and interviewing process: Plant Manager, Kevin Sullivan; Quality Control Manager, Duen Pagon; Tanya Peacock, HQ Quality Senior Field Representative for PBG International Affairs, from PBG 's HQ Quality Team in Somers, NY. Ms. Tanya Peacock reported to be covering in the absence of the Field Quality Manager, Bisi Oloruntoba, assigned to PBG-Orlando's manufacturing plant. Ms. Tanya Peacock established her credentials and familiarity with the firm's processes by reporting that she had previously been assigned to this specific plant as a Field Quality Manager before assumption of her current position.

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HISTORY (DAR)

The firm remains a manufacturer and distributor for bottled, canned, and bag in box carbonated flavored soft drinks, flavored tea beverages, fruit flavored beverages, and bottled water beverages.

Pepsi Bottling Group Incorporated (PBG) is a publicly traded company since March 1999. The Orlando site has been manufacturing and distributing Pepsi drink products since the early 1970's. The business registration for PBG is currently active in the State of Florida. In 1999 PBG spun off from PepsiCo Incorporated and PepsiCo retains an equity interest in PBG of about [redacted] percent. (b)(4) Pepsi-Cola Company, a division of PepsiCo, manufactures and sells beverage concentrate syrup and finished goods to PBG. PepsiCo also provides new product development, advertising, marketing, sales and promotional support to PBG. PBG Corporate Headquarters is located in Somers, NY. On August 4, 2009, PBG announced an agreement to be acquired by PepsiCo, pending required approvals. This transaction is expected to close in late 2009 or early 2010.

The facility is approximately [redacted] square feet of production and office space. Mr. Sullivan reported an annual local sales volume in excess of [redacted] for 2008. (b)(4)

The firm has [redacted] operations employees and [redacted] Managers/Supervisors. The hours of operation are (b)(4) 24 hours/day, 7 days/week. The beverage production line runs Monday-Friday and has 2 ten-hour shifts for bottled products and 3 eight-hour shift for canned products. When it is busy, employees work overtime on Saturdays. The distribution fleet runs 7 days/week to distribute finished product to warehouses and retailers. The fleet also picks up cans, lids and bottles at the suppliers. The Administrative office is open Monday through Friday from 8:00am – 5:00pm.

Post Inspectional Correspondence (DAR)

Correspondence should be directed to:
Mr. Kevin Sullivan, Plant manager
Pepsi Bottling Group
1700 Directors Row
Orlando, FL 32809

INTERSTATE COMMERCE/JURISDICTION (DAR)

Pepsi Bottling Group-Orlando manufactures a variety of beverage products. It receives its beverage concentrate (syrup), reported by Ms. Peacock to be used in all of its carbonated beverages, from [redacted]. Reference [redacted] dated 8/10/09, Order # 0097425, (Attachment #11, 1 page). Copies of document requested, but refused under (b)(4) aforementioned authority by Ms. Peacock.

Pepsi Bottling Group operates as a wholesale distributor of beverages to PBG-owned warehouses for subsequent retail distribution and also distributes product directly to retail outlets, including vending

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machines. The firm ships approximately [redacted] of finished products outside of the state of Florida. The product list was provided for review by Ms. Tanya Peacock: (b)(4)

Pepsi Brands	Dr. Pepper Brand	Mountain Dew Brand	Lipton Brand	Tropicana Brand	Fountain
Pepsi-Cola	- Diet Dr. Pepper	- Mountain Dew	- Lipton Brisk	- Tropicana Fruit Punch	- Crush, Diet Pepsi, Diet Pepsi Caffeine Free, Dr. Pepper, Lipton (various flavors), Mtn Dew (various flavors), Tropicana (various flavors)
- Diet Pepsi	- Diet Dr. Pepper Caffeine Free	- Diet Mountain Dew	- Lipton Iced Tea	- Tropicana Grape, Lemonade, Light Berry, Light Lemonade, Orangeade, Pink Lemonade	
- Caffeine Free Pepsi	Crush Brand	- Mountain Dew Code Red	MUG Brand	- Strawberry meteor	
- Caffeine Free Diet Pepsi	- Crush Orange	- Diet Mountain Dew Code Red	- MUG Root Beer		
- Pepsi Lime	- Diet Crush Orange	- Caffeine Free Mountain Dew	- Diet MUG Root Beer		
-- Diet Pepsi Max		- Diet Caffeine Free Mountain Dew	- MUG Cream Soda		
- Pepsi Vanilla	Sierra Mist Brand	- Mountain Dew LiveWire	- Diet MUG Cream Soda		
- Diet Pepsi Vanilla	- Sierra Mist	- Mountain Dew AMP			
- Pepsi Twist	Aquafina Brand	-- MDX			
- Diet Pepsi Twist	-- Aquafina	-- Diet MDX			
- Wild Cherry Pepsi					
- Diet Wild Cherry Pepsi					

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INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED (RLM)

Since the last FDACS contracted state inspection conducted on 4/21/09, the following changes in personnel have been implemented:

Carl Szyplula.....As Operations Manager, Mr. Szyplula will be responsible for overseeing the activities of the Production Manager, Tony Stanfield and the Maintenance Manager, Misal Ortega. This is a newly created position within the last 30 days. The Operations Manager reports to the Plant Manager, Kevin Sullivan.

Additional Persons Interviewed and Responsibilities Identified

Ed Ballina.....Vice President, Manufacturing Southeast Business Unit-Interviewed - 7380 Sand Lake Road, Suite 230, Orlando, FL 32819. The Plant Manager reports to Ed Ballina.

Tanya Peacock..... HQ Quality Senior Field Representative for PBG International Affairs-Interviewed-office based out of Somers, NY. Tanya Peacock is responsible for resolving quality related issues on an international basis and acts as an intermediary between the plants in the field and the HQ Quality Team for PBG. She indicated that there is an equivalent role on the Pepsi Corporation North America (PCNA) side and that they work collaboratively together to resolve quality issues. During the investigation, Ms. Peacock answered the majority of the questions about the consumer complaint and some of the firm's processes. Ms. Peacock reports to Gina McElgunn, Vice President of Worldwide Quality for PBG.

Bisi Oloruntoba..... Field Quality Manager PBG-Not Interviewed-responsible for resolving quality related issues for the Orlando PBG Bottling Plant and approving the plant's QC plan; she was not present during the inspection and was reported to be "out." Ms. Tanya Peacock covered for and in place of Ms. Oloruntoba.

Kevin Sullivan.....Plant Manager-Interviewed - responsible for the entire plant operations including production, quality, maintenance, warehouse operations, fleet operations and has a manager in each area identified that manages the aforementioned departments. Mr. Sullivan is responsible for the overall activities of approximately [REDACTED] employees and [REDACTED] managers and supervisors. Mr. Sullivan has been in this capacity for 1 ½ years. Mr. Sullivan reports to Ed Ballina-VP of Manufacturing SE Business Unit. (b)(4)

Duen Pagon.....Quality Control Manager-Interviewed-responsible for the quality of finished products; tests finished products, raw materials, and syrup that is blended with water; highlights issues that pose potential quality problems; works closely with production manager, warehouse manager, transport manager; oversees [REDACTED] hourly employees and [REDACTED] quality supervisors across 3 shifts. Mr. Pagon has been serving in this capacity for approximately 1 ½ months. Mr. Pagon reports to the Plant Manager. (b)(4)

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Lisa Yates.....Night Shift Quality Control Supervisor-Not Interviewed-responsible for quality control related activities on the night shift production line. Ms. Yates was the former Quality Control Manager. Ms. Yates reports to Duen Pagon, Quality Control Manager.

Tony Stanfield.....Production Manager-Not Interviewed-responsible for all production lines, staffing, scheduling, and the production of finished product. Mr. Stanfield is responsible for [REDACTED] hourly employees and [REDACTED] supervisors. Mr. Stanfield has been in this capacity for 8 months. Mr. Stanfield has begun reporting to Mr. Carl Szygula, Operations Manager within last 30 days. Prior to this he reported to the Mr. Sullivan, Plant Manager.

(b)(4)

Misal Ortega.....Maintenance Manager-Interviewed-responsible for all preventive maintenance of production line equipment and building repair and maintenance; Mr. Ortega is responsible for [REDACTED] hourly employees and [REDACTED] supervisor and has served in this capacity for 1 year. Mr. Ortega has begun reporting to Mr. Carl Szygula, Operations Manager within last 30 days. Prior to this he reported to the Plant Manager.

(b)(4)

Mark Rogers.....Warehouse Manager, Day Shift-Not Interviewed-responsible for warehouse staffing, scheduling, inventory control, and day shift loading operations; Mr. Rogers is responsible for a combined [REDACTED] employees and a combined [REDACTED] supervisors. The responsibility for oversight of these employees is distributed between Mr. Mark Rogers and Mr. Jim Rogers, who are reported to not be related to one another. Mr. Mark Rogers has served in this capacity for 2 ½ years. Mr. Mark Rogers reports to the Plant Manager.

(b)(4)

Jim Rogers.....Warehouse Manager, Night Shift-Not Interviewed-responsible for overseeing night shift loading operations and shares responsibility with Mark Rogers for the management of the aforementioned [REDACTED] employees and [REDACTED] supervisors. Mr. Jim Rogers has served in this capacity for 3 months. Mr. Jim Rogers reports to the Plant Manager.

(b)(4)

Richard Dixon.....Fleet Operations Manager-Interviewed-the fleet operations manager is responsible for preventive maintenance tasks and repairs to fleet of PBG vehicles; Mr. Dixon is responsible for # [REDACTED] hourly employees and no supervisors. Mr. Dixon has served in this capacity for 1 ¼ years. Mr. Dixon reports to the Plant Manager.

(b)(4)

Richard Hernández.....Transport Manager-Interviewed-responsible for all inbound/outbound trucks for the state of Florida; manages the drivers and all contract common carriers if they are used to ship loads. Mr. Hernández reports to Ronnie Day, Regional Transport Manager.

Ronnie Day.....Regional Transport Manager-Not Interviewed-per Mr. Hernandez, Mr. Ronnie Day is responsible for coordinating outbound with inbound loads for efficient economical use of the vehicle fleet that is housed at various locations throughout the state of Florida.

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██████████..Raw Materials Coordinator-Interviewed-reviews the production schedule for previous week and orders all primary (bottles, cans, lids, caps) and secondary (boxes, packaging, labels) packaging materials needed for the next production run. (b)(6)

FIRM'S TRAINING PROGRAM (RLM)

Bisi Oloruntoba, Field Quality Manager for PBG and Lisa Yates, Night Shift Quality Control Supervisor and former Quality Control Manager are HACCP certified. We reviewed HACCP training certificates for Ms. Oloruntoba and Ms. Yates dated 1/23/09 and 4/2/09 respectively. Mr. Pagon, current Quality Control Manager and Mr. Sullivan, Plant Manager have not yet attended the HACCP training programs. Mr. Pagon provided copies for review of Ms. Oloruntoba's and Ms. Yates' latest HACCP training certificates. Mr. Sullivan and Mr. Pagon further explained that all new and existing employees receive initial GMP and safety training, monthly safety training, and annual refresher GMP training conducted by the HR department. Mr. Sullivan stated that most new hourly employees start in warehousing operations and eventually move into production jobs after that. Ms. Peacock further explained that Ms. Oloruntoba, Field Quality Manager for PBG-Orlando signs off on the plant's Quality Control (QC) plan.

MANUFACTURING/DESIGN OPERATIONS (RLM)

The current inspection covered the firm's receiving, storage, water treatment, processing, packaging, closing, finished product storage, distribution processes, waste management, pest control, training, customer complaints, and recall procedures.

In addition, the inspection covered the following products, systems, processes, documents and record review: the bottled, canned, and bag in box carbonated flavored soft drinks, flavored tea beverages, fruit flavored beverages, and bottled water beverages; the blending of beverage concentrate with reverse osmosis processed municipality supplied water; the receipt, storage, and testing of ██████████ (b)(4) used in finished product formulas; the receipt, storage, filling, sealing, and quality control processes associated with firm's handling of incoming primary packaging material (cans, bottles, lids, caps) and associated filling process used in the firm's canned beverage line.

The firm's Plant Manager, QA Manager, and HQ Quality Senior Field Representative for PBG International Affairs confirmed details surrounding the production of the identified lot in CC#93105 to include: the date of production, quantity produced, distribution pattern, as well as the quality control processes in place that led the firm's management team to a preliminary conclusion, based on the Plant Manager and QA Manager's reported investigative efforts, that the alleged foreign object did not originate in their manufacturing plant. The HQ Quality Senior Field Representative for PBG International Affairs confirmed that the complainant had disclosed to the Consumer Affairs Coordinator, the retention of legal counsel surrounding the complaint (CC#93105) of the alleged foreign object in the can of Diet Pepsi.

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Mr. Pagon provided for review a copy of the firm's PCNA Quality Procedures-Product Safety Procedure, dated 1/22/09. It revealed the firm's identified physical and chemical hazards and associated critical control points for processing. In addition, critical limits, corrective actions, responsible employees, and verification procedures were identified by review of this document. Copies were requested and refused by Ms. Peacock under the aforementioned authority.

Mr. Sullivan stated that the firm processes and distributes about [REDACTED] of its beverages in the following containers: carbonated soft drinks in bag in box packaging for fountain drinks at retail outlets, gallon jugs, 2 liter plastic bottles, 16.9 fl oz plastic bottles, and 12 fl oz cans; the firm processes [REDACTED] of its beverages in the form of non-carbonated juice drinks that are less than [REDACTED] juice; and processes [REDACTED] of its beverages produced in the form of bottled water. The firm manufactures these beverages on 3 bottle lines and 1 can line. Bottled water is produced on 2 of the 3 bottle lines when bottled water is produced. The can line, fills cans at a rate of [REDACTED] cans/minute.

(b)(4)

Ms. Peacock provided the firm's concentrated syrup product list for review and copies were refused of all documents under aforementioned authority. Clarification with Mr. Sullivan, and review of product syrup list, reflects the aforementioned products are currently manufactured on premises in 12 fl oz cans, gallon jugs, 2 L plastic bottles, 16.9 fl oz plastic bottles, and bag in box packaging for retail and wholesale distribution.

On 8/4/09, the firm was manufacturing Diet Pepsi in 12oz cans and Pepsi in 2L bottles at the time of the inspection. Orange Crush cans were observed on the can line from the truck to the depalletizer and vacuum sorter. The vacuum sorter was reported by Mr. Sullivan and Mr. Pagon to ensure the cans are upright and rejects cans that have dents on the rim. They further reported that the cans, with dents on the rim and those not oriented in an upright position are ejected and separated out of the production line by falling into a plastic bin beneath the vacuum sorter.

Receiving:

On 8/04/09, the firm was processing on all 3 of the carbonated bottled beverage lines and on the single carbonated canned beverage line, (**Attachment # 1 and # 2, 1 page**). We were unable to witness the offloading of any incoming packaging or raw materials during the inspectional walkthrough. Mr. Sullivan stated that any incoming raw materials would arrive via trailer or tanker and be sealed with an official seal that is noted on the BOL associated with that incoming load of raw materials. He further stated that this seal number is verified by the security guard (multiple employees, one FTE) in addition to the tag number on the truck trailer at the front gate to the plant. Gate guards are posted on 3 shifts from 5am-2pm; 2pm-11pm; 11pm-7am. Ms. Peacock indicated that a reconciliation of raw goods occurs after offloading of raw materials and occurs within 24 hours due to the volume of product arriving. If any discrepancies are identified, the raw material is isolated pending resolution with the firm from which the shipment originated. Mr. Sullivan and Mr. Pagon jointly stated that there is no QAP or critical control point identified for the receiving of primary packaging materials and further elaborated, when questioned, that the only check that occurs is a visual check for dented or damaged cans that come off of the tractor trailer.

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Ingredient Inspecting

Mr. Ballina stated that PepsiCo has a Global Procurement Dept. that audits the suppliers of its raw materials for all PBG plants. The last Global Procurement Dept. audit of PBG-Orlando's supplier of cans and lids, [REDACTED] a subsidiary of [REDACTED] was reported by Ms. Peacock to have occurred on June 15, 2009 and indicated she was not aware of any quality related issues. Investigator Racioppi and I also reviewed a certificate of analysis (COA) for 12 oz cans supplied by [REDACTED] dated Jul, 2009. Investigator Racioppi and I also reviewed BOL # 13159194 and BOL # 10855610 for the cans and lids associated with the lot identified in CC # 93105 that originated from [REDACTED] two locations, (**Attachment # 12, 2 pages**). Furthermore, Investigator Mundy and I viewed several BOL associated with the distribution of the affected lot identified in CC #93105, (**Attachment # 13, 3 pages**). The PepsiCo Global Procurement Dept. audits were reported to cover all packaging materials, [REDACTED] and [REDACTED] by Ms. Peacock. The beverage syrup concentrate that is mixed with other ingredients at PBG to obtain the finished beverage product is obtained from PepsiCo. The Global Procurement Dept. was also identified to negotiate the purchase of raw ingredients and packaging materials on behalf of PBG. Mr. Ballina further stated that if there is a deviation noted in any of the raw materials, then PBG would follow corporate protocol for reporting quality related issues. (b)(4)

Mr. Ballina indicated that the entire company has switched over to a 3rd party auditor utilizing the [REDACTED] Process in March 2009. This was reported to have occurred because one of their larger customers was requiring 3rd party audits of processes as a condition of doing business with them. (b)(4)

Mr. Pagon stated that the [REDACTED] is received and transferred via tanker truck to a [REDACTED] gallon storage silo located external to the building, then piped into the building from the silo to the syrup tanks for blending the [REDACTED] with beverage concentrate syrup. The blended product is pumped through piping into a device identified as [REDACTED]. In the [REDACTED] and [REDACTED] are added to the beverage concentrate syrup and [REDACTED]. The [REDACTED] syrup tanks range in size from [REDACTED] gallons. Mr. Pagon also indicated that each lot of [REDACTED] that is received at PBG has 3 samples collected from it. One sample is for analysis of BRIX content. The other two samples are retained samples per PepsiCo policy. One is retained for 3 months and the other is retained for 6 months. Mr. Pagon further provided documents indicating that tanker truck is inspected upon delivery for evidence of rodent or pest contamination and inspects the [REDACTED] before and after delivery for off-odors or foreign materials. (b)(4)

Mr. Pagon stated that the firm receives its beverage concentrate (syrup) from PepsiCo. Ms. Peacock stated that the beverage concentrate (syrup) is received in [REDACTED] gallon drums. This beverage syrup concentrate is mixed with [REDACTED] and [REDACTED] then referred to as the finished product prior to the bottling process. (b)(4)

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Further investigation revealed disclosure of a corporate PBG document provided for review by Mr. Sullivan and Ms. Peacock indicating that there is a program in place that authorizes any associate to submit a corrective action resolution request, thereby generating a unique sequential number assigned by the QA Manager for tracking purposes. Reviewed the document that reads in part: *** "PBG Corrective Action Program, QRP-001, Approved by Gina McElgunn, issue date: 08/30/01, pages: 13"*** This document further elaborated that the Quality Manager is responsible for the overall administration of the corrective and preventive action system. Copies of this document were refused under the aforementioned authority by Ms. Peacock.

Storage and Warehousing

Packaging Materials

Packaging materials, primary (bottles/caps & cans/lids) and secondary (labels for bottles/boxes for cans/shrink wrap) are staged and stored in separate areas of the PBG-Orlando plant. Primary packaging materials are received on high density plastic pallets under the just in time inventory strategy thereby reducing the amount of inventory that the warehouse has to store prior to production. Once received, they are staged and stored on pallets adjacent to the bulk receiving depalletizer in-feed area of the warehouse and are rotated on a first in first out basis. Plastic bottles are received with a shrink wrap cover over them (per Plant Manager, for stability purposes) as opposed to the aluminum cans being received on a banded pallet with high density plastic slip sheets in between each layer of can and without a shrink wrap cover. The Plant Manager indicated that the shrink wrap is removed from the bottles 48-72 hours after receipt and right before incorporation onto the conveyor line for processing.

Bottle caps and can lids are received in a protective over wrap and are manually loaded into dispensers that feed into the respective seaming devices for the bottle and can lines. Mr. Pagon stated that bottles or cans that fall onto the floor during processing are considered trash and excluded from further processing. They are sent to a bailer where they are compacted and recycled for their plastic or aluminum content.

Secondary packaging materials are staged and stored, adjacent to the 2 liter and 16.9 fl oz bottle descrambler equipment, on open metal shelving units that are 18 bays long by 3 bays high. Secondary packaging materials are received on wooden pallets usually in cardboard boxes, paper packaging over wraps, or shrink wrapped. Canned beverage packing boxes are available in 6, 8, 12, 24, and 36 pack varieties. Materials are removed as needed from the metal shelving units by fork lift and staged in their respective usage area for loading into the labeling equipment of 2 liter and 16.9 fl oz plastic bottles and are loaded into the exterior box packaging machine for the 12 fl oz beverage cans.

[REDACTED]
[REDACTED] is received and transferred via tanker truck to a [REDACTED] gallon storage silo located external to the building, then piped into the building through closed rinsers pipes to the syrup

(b)(4)

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tanks. It is then transferred to the 2 blending tanks [redacted] for blending with other ingredients by date received and with assigned batch number.

(b)(4)

Beverage Concentrate Syrup

Beverage syrup concentrate was reported by Ms. Peacock to be received and stored in [redacted] gallon drums inside the warehouse. Ms. Peacock indicated that some concentrated beverage products require storage in refrigerators ([redacted] beverage concentrate mixes). Those products that require refrigeration are palletized and stored behind one of four refrigerated doors opening into a temperature controlled room further divided into two large refrigerators.

(b)(4)

[redacted] is received by tanker truck and stored external to the building in large tanks where it is piped into the building for use during the bottling process.

(b)(4)

Water

The firm receives its water supply from the Orlando Utility Commission. We reviewed the water bill for the time period 4/17/09 to 5/19/09 for 2 commercial use water meters and 2 irrigation water meters. PBG Orlando treats all of the water that is used in its finished products by means of an [redacted] water purification unit and [redacted] treatment.

The treated water is stored in two separate locations depending upon the processing of the municipal water supply. Treated water used for the bottle line is stored in an [redacted] storage tank where it is circulated until use on the water bottle line. The water for all other beverage lines is stored in the [redacted] storage tank until use on all other beverage lines, (Attachment # 3, 1 page).

(b)(4)

Batching (Syrup Processing)

The batching occurs in a multi-step process where the [redacted] is pumped into the syrup room and stored in one of six storage tanks ranging in size from [redacted] gallons; [redacted] is transferred from the storage tanks to the production lines through a [redacted] where [redacted] is added, water in [redacted] ratio of water to syrup, dry ingredients, and soluble additives are mixed to create what is referred to as the finished syrup product, as stated by Mr. Pagon.

(b)(4)

The batching process as identified above is linked to the water treatment process by incorporation of treated water into the finished syrup.

Water Testing:

Ms. Peacock stated that the raw municipal water supply and the PBG reverse osmosis water supply samples are analyzed quarterly through an internal process in [redacted] and through a 3rd party auditor, [redacted]. MS Peacock stated that Compliance Design handles the coordination of water sample submissions to all state health departments that PBG-Orlando distributes its bottled water beverage supply to. Reviewed results of

(b)(4)

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[REDACTED] water samples and 4 raw municipality water samples that had been sent for analysis to [REDACTED]. Mr. Pagon stated that internal testing of water occurs for microbiological contaminants, wet chemistry components, volatile organic compounds, cations, anions. We reviewed the most recent quarterly water testing results for samples taken on 3/24/09 that were tested in [REDACTED]. Results are evaluated against PepsiCo Treated Water Ingredient Specification 17P45BTR. (b)(4)

Processing-CCP #1:

The firm identified the processing phase as the first step in their beverage manufacturing process with a critical control point as noted in the PCNA Quality Procedures-Product Safety Procedure, dated 1/22/09 and approved 2/6/09, (**Attachment # 2, 1 page**). Copies were refused under previously disclosed authority by Ms. Peacock. The processing phase encompasses the transfer of [REDACTED] from the 6 storage tanks in the syrup room through a syrup screen and the subsequent filling of primary packaging materials. The syrup screen, identified in CCP#1, is to be inspected at the start of production each day or during the 1st changeover of syrup in excess of 24 hours. (b)(4)

The critical operating limits assessment, associated with CCP #1's, syrup screen (physical hazard) include a check by the operator to verify that the syrup screen is seated properly, intact, and without any rips or tears. The corrective actions identified to be implemented, if critical control limits are exceeded, for physical hazards are: stop production; notify supervisor; hold product back to the last good check as identified in referenced documents (NCP-002 and NCP-003).

The operator is to document that a screen check occurred on the batch sheet and then the information is recorded in an electronic database known as [REDACTED]. (b)(4)

[REDACTED] database is a master list hold report that tracks the disposition of products put on hold and tagged out with a hold tag due to quality related issues. Per Mr. Pagon, the [REDACTED] database is only accessed by the quality department staff and the release of products from a hold status only occurs by the Field Quality Service Manager. There is no separate identified documentation to track the supervisory responsibility for the disposition of product. The technician releases the product on hold based on a verbal authorization from the Field Quality Service Manager. (b)(4)

The processing phase's critical control points are verified through daily record reviews, quality audits, and review of consumer complaint data by the Quality Manager.

Reviewed batch report ID # 1010903-syrup (recipe and batch run associated with CC #93105) for the recipe of Diet Pepsi BC (bottles/cans) destined for tank #13 and using concentrate tank #2, dated 5/24/09 at 8:36:48 am and ending 5/24/09 at 9:18:08am with test data as follows: [REDACTED]. [REDACTED] Copies requested and refused by Ms. Peacock under aforementioned authority. (b)(4)

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Filling-CCP #2:

The filling process was identified by the firm to have a biological hazard associated with [REDACTED] that is incorporated into the [REDACTED] water storage tank. The [REDACTED] processed water is recycled through a storage tank pending use on the bottled water line and the beverage line. When needed the water is transferred to enable blending with other components to yield a finished syrup. Primary packaging supply containers are advanced along the conveyor system into the filler device and are filled with the finished syrup and [REDACTED] and are then closed (sealed with lids or caps). (b)(4)

The biological hazard associated with CCP #2, Filling, [REDACTED] is to be monitored at start up and with hourly checks on finished product. The critical limits identified for [REDACTED] is that it must be maintained between [REDACTED] (US and Canada), at the filler device. The corrective actions to be implemented if critical limits are exceeded are: correct the deficiency before starting operations; hold product back to last good check (reference document NCP-002 and NCP-003). (b)(4)

A critical operating limits assessment, associated with CCP #2 (a chemical hazard) for the Filling Process, indicates that [REDACTED] are used to confirm test results are acceptable (pass). [REDACTED] are used to check the finished product (all diet beverages except juice containing and nutritive sweetener blends) for presence of sugar at the start of each production run and at tank change. The corrective actions identified to be implemented if critical control limits are exceeded for chemical hazards are: stop production; notify supervisor; hold product back to the last good check as identified in referenced documents (NCP-002 and NCP-003). (b)(4)

The employees identified to be responsible and records to complete are the operator and quality line records and/or LMS and the results should be recorded in Hold Tracker. Verification of this process is accomplished through the on-line [REDACTED] monitor, daily record, and quality audits conducted by the quality department. (b)(4)

Packaging:

The packaging process refers to the primary packaging materials received through the bay doors in bulk receiving. Plastic bottles and cans are received secured (either wrapped in plastic wrap or banded) to the pallet and are unloaded from the tractor trailer by means of a cable pulley mechanism known as [REDACTED]. The entire contents of the tractor trailer are offloaded via [REDACTED] and staged in the depalletizer in-feed area. (b)(4)

Depalletizer

Mr. Pagon stated the [REDACTED] breaks down a pallet of cans with 21 layers containing [REDACTED] cans/pallet at a rate of [REDACTED] cans/min averaging [REDACTED] per slip sheet and that the cable conveyor is [REDACTED] feet long, from the slip sheet remover to the [REDACTED] air rinsers. Mr. Sullivan stated that an entire tractor trailer full of cans could be processed on the conveyor line at any given time. (b)(4)

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As the cans transition from the depalletizer in-feed area into the [REDACTED] the bands securing the cans to the can pallet are severed by a band cutter, removed from the pallet, are shredded and piped into a box for recycling. The [REDACTED] raises the pallet to expose one layer of cans at a time by means of [REDACTED] first removing the pallet case cover, followed by a layer of cans, then the [REDACTED] exposing the layer of cans beneath. The layer of cans are sandwiched between two arms on the [REDACTED] and the high density slip sheets are pulled out from under the layer of cans while simultaneously moving the entire layer of cans onto a multi-line conveyor belt. The process repeats itself until the entire pallet of cans is transferred from the pallet onto the multi-line conveyor system.

(b)(4)

Vacuum Transfer Unit

Ms. Peacock, Mr. Sullivan, and Mr. Pagon collaboratively stated that the cans move along the multi-line conveyor system, passing under the vacuum transfer unit, that exerts a vacuum force of [REDACTED] on a water column reading to the rims of the cans, and are transferred across a void on the multi-line conveyor belt to another multi-line conveyor that merges into a single line conveyor system. Cans that are overturned, fall into a plastic collection bin for compacting and then recycling.

(b)(4)

Mr. Sullivan and Mr. Pagon stated that the vacuum transfer device would allow cans with a defective rim, a foreign object in them, or overturned cans to be excluded from continuing along the conveyor system, however review of the vacuum transfer unit specifications read in part *** "the chief purpose of the unit is to allow fallen cans to drop out of the conveying environment (usually, prior to a single filling function). The transfer is neither designed nor intended to function as a bent flange detector or a damaged can reject device"***. Copies of the document were requested but refused by Ms. Peacock under the aforementioned authority. Mr. Sullivan stated that the can specs have changed over the years and that the cans are now lighter than they used to be.

Cans are transferred across the void on the multi-line conveyor system, open end upright. The cans move along the multi-line conveyor until they merge into a single line on the conveyor system.

The plastic beverage bottles follow a similar distribution pattern from [REDACTED] to the [REDACTED] that moves the bottles into their filling station. The bottles fall off of a mass conveyor into a hopper that unscrambles the bottles and orients them into the proper position allowing the bottles to be blown along, by a stream of air, on the neck ring of the bottle, thereby advancing the bottles along the air conveyor line to the filling device. There are 4 air conveyor lines and two of them are used for 2 liter bottles with the remaining being used for the 16.9 fl oz bottles.

(b)(4)

Rinsing

The firm utilizes a combination of rinsing devices to cleanse the inner part of bottles and cans prior to filling. The bottle line utilizes a water rinsing system and the can line uses an [REDACTED] air rinser that sprays a pre-filtered stream of air into the can to remove particulate matter. Both methods are designed to remove particulate matter from the inside of the containers prior to filling, (Attachment # 4, 2 pages).

(b)(4)

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Ms. Peacock, Mr. Sullivan, and Mr. Pagon collaboratively stated that the [REDACTED] air rinser device was installed in the firm, for use on its can line, approximately 5 years ago as a green initiative by Pepsi to conserve water. Pressure and equipment are specified by Pepsi. Mr. Sullivan and Mr. Pagon collaboratively discussed and stated that the QA technician performs a visual pressure check hourly on the [REDACTED] air rinser and documents this on the can line control record. It is documented as pass or fails in the block identified as [REDACTED]. Mr. Sullivan, Mr. Pagon, and Ms. Peacock did not know why the aforementioned terminology was used and stated [REDACTED] is not used in the water rinsing process of the cans or bottles. Ms. Peacock stated they would address it. (b)(4)

Ms. Peacock, Mr. Sullivan, and Mr. Pagon collaboratively stated and supplied the specification sheets associated with the [REDACTED] air rinser. They collaboratively stated that the air rinsers spray a high pressure stream of air into the cans to wash any debris out of the can before it is filled. (b)(4)

Further review of the specification sheet for the [REDACTED] air rinser with 4 nozzles read in part *** "spray a compressed high pressure stream, [REDACTED] per nozzle, of positively charged and filtered plant air to blow particulate matter out of the cans as they enter the air rinser from an overhead conveyor, via [REDACTED] gravity track fittings, which rotates them in a horizontal orientation with the open end angled down, at a rate of [REDACTED] cans/minute. The cans are then rotated back to the horizontal position and exit the rinser. Debris from the cans is expelled into a recirculating air stream where it is separated and collected for inspection" ***, (Attachment # 4, 2 pages). (b)(4)

Ms. Peacock, Mr. Sullivan, and Mr. Pagon collaboratively stated that any debris would fall out into a hopper with a metal filter screen that draws circulated air through 2 additional filters below. Mr. Pagon stated that the filters are changed every month with the clean in place procedures, and when questioned if the metal filter screen is ever examined for the type of debris that is air rinsed out of the cans, Mr. Pagon responded, "No". Mr. Pagon further stated that the filters are looked at when changed, but it is not documented on the form.

From the air conveyor, bottles enter a bottle rinser and are sprayed with pressurized water jet, drip dry, the make their way to the bottle line filler.

Filling-CCP #2

Ms. Peacock, Mr. Sullivan, and Mr. Pagon collaboratively stated that when the cans exit the [REDACTED] air rinser, cans are fed via [REDACTED] conveyor into the [REDACTED] filler bowl (same concept for bottle line). Cans are cold filled [REDACTED] Fahrenheit) to a target range of 12 fl oz. (Attachment # 1 and # 2, 1 page each). When the designated fill level is reached, a sensor triggers the filler valve to shut off. Filler valves operate independent of one another. (b)(4)

Mr. Pagon stated that there are several quality assurance processes (QAPs) in place to evaluate the finished product produced including beverage BRIX, beverage [REDACTED], analysis of water supply, [REDACTED] and package pressure, and [REDACTED] analysis of finished product. (Attachment #

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5, 6 pages). Mr Pagon stated that a lab tech pulls a sample of the first can produced, an hourly sample, and a "last can produced" sample to confirm that the finished product corresponds with the specification standards set by PepsiCo. These same parameters are checked by the online monitoring system every 15 seconds.

If the sample is out of specification, then an alarm sounds causing the cessation of the production process. The lab tech will pull the last sample that made it through the filler device, after the online monitor has analyzed it, and perform a manual check of the last can out of the filler. If there is a problem between the manual check and the in-line monitor check resulting in out of range specifications, then shutdown occurs and trimming of equipment takes place and adjustments are made as necessary during processing. Mr. Pagon stated that the trimming of equipment occurs because the manual check is more sensitive than the in-line monitor.

Mr. Pagon stated that a manual check is performed because the [REDACTED] (online monitoring system's membrane filter) [REDACTED] can sometimes clog, which would give an out of specification result. The lab staff performs the manual check and if it is out of specifications they pull a second product off the same line and verify that the product's specifications are appropriate. If they are appropriate, then the system is started up and the first can sample after start-up is pulled for manual analysis and compared to the [REDACTED] online monitoring sample results. (b)(4)

Mr. Pagon stated that there were two scenarios that would cause the production line to halt: (1) failure of the in-line monitoring system to collect a sample (a result of malfunction), or (2) an out of specification result noted by the online monitoring system or lab tech. Mr. Pagon further clarified the amount of time that the production line could be down, leaving open cans exposed on the production line until resumption of production and movement of cans, by stating that the lab tech would conduct a BRIX test, which takes a couple minutes and [REDACTED] which takes approximately 7 minutes. He further elaborated that the amount of time it takes before the production line can start up again depends on whether it is a mechanical/computer malfunction scenario versus a true out of specification scenario. If an out of specification scenario is identified, the filter tank is dumped. (b)(4)

Mr. Pagon further stated, when questioned about control standards that the buffers used during manual checks of [REDACTED] are changed daily. In addition, the in-line monitor system uploads the data into the [REDACTED] Computer System that can be reviewed by corporate quality control in real time. The following documents were reviewed by Investigator Racioppi: Product Safety Plan, "PCNA Quality Procedure," PROC 4.2.3.1, issued 1/22/09, Revision #7; this procedure is generated by PBG headquarters and includes plant-specific information. Bisi Oloruntoba reviews and approves this procedure. No discrepancies found. (b)(4)

Sanitation and Clean in Place Processes(CIP)

Mr Pagon stated that sanitation occurs, packaging area and conveyors (bottles and can lines), weekly. He stated that the firm alternates between [REDACTED] uses [REDACTED] per gallon of water) and [REDACTED] per gallon of water). Investigator (b)(4)

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Racioppi and I reviewed the document "PBG Orlando Sanitation Procedures [redacted] Food and Beverage Division". Mr. Pagon further stated that the filler bowl has a clean in place sanitation procedure. Review of the spec sheet associated with the filler device indicated that it was a complete closed loop CIP circuit. The filler bowl can be hot or cold sanitized and circulates food grade cleaning agents through the system also weekly.

(b)(4)

Closing

The closing process, identified in the PBG Product Safety Procedures document, is applicable to all carbonated soft drinks (CSD's), still drinks (non carbonated flavored beverages), and Aquafina bottled water produced in the Orlando plant. Mr. Pagon identified several QAPs that are associated with this process including: lot code, tamper evidence, double seam check, torque, PAT/SST, and [redacted] (cans/bottles if installed), package coding, net content, warmer temperature, and air content (cans).

(b)(4)

Seaming Device

After exiting the filler bowl, cans next enter the seamer device, and are double sealed with a metal lid. The seaming device is manually supplied with metal lids through a filling sleeve that feeds directly into the seaming device. Ms. Peacock stated and illustrated that the seaming device seals the can lid with a double seal first by creating a curl around the open end of the can and then by pressing the lid edge down over the can curl. Mr. Pagon stated that bottles are capped in a twisting motion at a rate of [redacted] bottles per minute on the bottle line. Several maintenance records, preventative maintenance records, calibration records, and service reports were reviewed as part of the quality related documents associated with the seaming device, (Attachment # 6, 2 pages).

(b)(4)

Cooling/Warming

As previously stated by Mr. Pagon, the cans are cold filled [redacted] Fahrenheit) because of the of the [redacted] process, to a target volume range of 12 fl oz.

(b)(4)

Warming

After cans are cold filled at [redacted] degrees Fahrenheit and sealed, they progress along the conveyor upside down (for seal integrity check) through a warming bath ([redacted] degrees Fahrenheit). Mr. Pagon stated the purpose of the warming bath is to bring the cans back to room temperature and within approximately [redacted] degrees Fahrenheit above dew point. He further stated that this would reduce sweating of the cans through their cardboard packaging.

(b)(4)

Labeling-CCP#3

The cans exit the warming bath upside down, eventually turning upright on the conveyor after passing through the can coding device, and are oriented upright prior to passing through the [redacted] device. Cans are coded as noted in the manufacturing codes section of this report with a best buy date (month day year), military time, plant code, month, day, and year. Mr. Pagon provided a copy of the can coding placard on the wall adjacent to the can coder upon request on the first day of the inspectional walkthrough, (Exhibit # 1, 1 page).

(b)(4)

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Device

The cans progress along the conveyor and through the [REDACTED] device. The [REDACTED] device verifies the volume of the cans and ejects the low volume cans. A review of the [REDACTED] specification document revealed that the device uses [REDACTED] to inspect for under-filled or over-filled containers. A reject threshold is established and as cans pass through the [REDACTED] device, a [REDACTED] passed through the cans to a detector on the other side. It works on the principle of [REDACTED]

(b)(4)

If a higher than established threshold amount reaches the detector on the other side of the passing can, it is deemed under-filled and is ejected by the [REDACTED] device. Investigator Racioppi and I reviewed the [REDACTED] specification document and maintenance documents associated with the [REDACTED] device. Investigator Racioppi and I also witnessed Mr. Ballina demonstrating the passing of a red can and a green can through the [REDACTED] device to demonstrate the reject process. The red can was identified as the under-filled can while the green can was the control can. The [REDACTED] device rejected the under-filled red can while allowing the green can to pass. Mr. Pagon stated that this manual check is performed at least once every hour. Copies of these documents were requested, but were refused by Ms. Peacock under the aforementioned authority (Attachment # 7, 2 pages).

(b)(4)

Labeling-CCP#3

Label verification was identified by the PCNA Quality Procedures-Product Safety Procedures, dated 1/22/09 as the 3rd critical control point for the firm's processing line for bottles and cans, (Attachment # 2, 1 page). It was further identified by this document that the monitoring of the package label and contents should occur at start up, roll changes, and upon selection of pre-labeled primary packaging containers on each pallet. The critical limit associated with this step is that package content must match package label. The corrective actions to be undertaken if critical limits are exceeded are: (1) stop labeling/production, (2) hold product back to last good check (per documents NCP-002 and NCP-003), (3) correct situation. The document further identified the employee responsible for this task as the operator and the records associated with this as the self labeling (PIF-001) and the pre-labeled primary containers (BVF-035).

The document further identified that verification of this procedure is accomplished by a daily review of records, quality audits, trade samples, and review of consumer complaint data.

Casing/Palletizing

The cans then progress to a packaging device that packs the cans in their respective secondary cardboard packaging box. Mr. Pagon stated that the secondary packaging box is imprinted with the same code as the can and that the time is based on when packed in the box. It could be a few minutes later than the can.

Product Storage/Warehousing

After cans are packaged in their respective secondary packaging boxes, they are stacked on a pallet and are shrink wrapped. The shrink wrapped product is then staged and stored in the warehouse by

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product stability. Products were reported by Mr. Pagon to be rotated out of the warehouse based on an inventory report generated with code dates that identifies which pallets of cans needed to be pulled from inventory enabling the older product to be sold before the expiration date. Mr. Pagon stated that for local routes, pallets of product are built by hand and are loaded onto the delivery trucks. He also stated that deliveries for the transport routes are built by using whole pallets of product.

Shipping/Distribution

Mr. Sullivan stated that the firm distributes its products wholesale, to 3rd party vending companies that further distribute to retail locations throughout the state of Florida. He also stated that the firm distributes its products internally to satellite warehouses predominately in Central Florida at the following locations: Winter Haven, Melbourne, Daytona Beach, Ocala, and Ft. Pierce. He also stated that internal transfers of finished product do not have a direct retail outlet component. Mr. Sullivan clarified that there are about [redacted] satellite warehouses in Florida with the largest being located in Miami, Tampa, Jacksonville, Gainesville, and Ft. Myers. (b)(4)

Pest Control

Pest control management is contracted through [redacted] subcontracts the servicing of PBG-Orlando to [redacted]. We reviewed the most recent service report, service order # 4738353, dated 7/28/09 and observed that the contracted firm serviced the interior rodent stations between the hours of 10:03 am – 3:30 pm and serviced the building exterior perimeter rodent stations between 11:07 am – 3:45 pm. There was no rodent activity noted identified on the service report. A map of the rodent stations was provided by Mr. Pagon, (Exhibit # 2, 3 pages). During the inspectional walkthrough, we observed no rodent activity in the interior facility, the exterior building perimeter, or along the fence line, (Exhibit # 3, 1 page). Reviewed Pest Control Records dated July 21, 2009 for: (b)(4)

[redacted] Interior Rodent Traps
[redacted] fence-line Rodent Station and treatment for Exterior perimeter
No activity recorded per Service Order 4738353 (b)(4)

Reviewed Pest Control Records dated July 28, 2009 for:
[redacted] Rodent Traps and [redacted] Rodent Bait Stations
No materials applied (b)(4)
No activity recorded per Service Order 4738351

Ms. Peacock, Mr. Sullivan, and Mr. Pagon collaboratively stated that the plants management communicates with the service technician face to face to discuss any findings after the service treatment is completed. They further stated that they work with the pest control company to minimize infestations.

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MANUFACTURING CODES (DAR & RLM)

Manufacturing codes are stamped on the bottom of the cans and on the top of the bottles. The code is as follows:

Best Taste Buy Date (Month Day Year)

Military Time (within a few minutes of filling) Plant Code Date of Fill Year

For Example: *May 10 10* = Best Taste Date of May 10, 2010

1424ES08049 = Military Time of Manufacturing (14:24)/ES = Orlando Plant
Code/08049 = August 4 2009

Ms. Peacock, Mr. Sullivan, and Mr. Pagon stated and clarified jointly that the shelf life of beverage products is determined by product profile and packaging and is further derived from a chart established by PepsiCo known as "Best Taste Limits". They further stated that as the bottler, they abide by PepsiCo standards. The "Best Taste Limits" data are manually entered by a machine operator and lab tech into a computer that generates the manufacturing codes that are imprinted on the bottom of cans, (**Exhibit # 1, 1 page**).

COMPLAINTS/RECALL PROCEDURES (DAR & RLM)

On 8/05/09 Investigator Racioppi and I, reviewed the consumer complaint log (a single sheet computer printout) for the PBG-Orlando facility for the previous 2 years plus current year. Consumer complaints for the date ranges of 1/3/2007 to 7/24/2008 and present year were reviewed. We observed a total of #13 complaints of alleged foreign objects in beverage cans. Of the #13 complaints, two were identified by Ms. Peacock to be "unidentified foreign objects." We also reviewed the thirteenth entry on this sheet of paper referencing FDA CC #93105. A copy was requested, but was refused under the aforementioned authority. It was identified in part as follows:

*** "(Reference # 012071626A P), (Received-7/24/09), (Item: 12CNDP), (12INFC10ES), (MFG Code-Sep07091417ES0529) (Contacted her attorney and the FDA)" ***

We confirmed with Ms. Peacock, Mr. Sullivan, and Mr. Pagon that this was a verbatim statement and they answered in the affirmative. Ms. Peacock further stated that this was an ongoing investigation and so far their investigation had not determined a root cause. We further clarified if there was any documentation available for us to review to support their assertion that an investigation had been started regarding this matter. Ms. Peacock directed Mr. Pagon to retrieve an internal e-mail document for our review, (**Attachment # 8, 1 page**). A copy was requested, but was refused under the aforementioned authority.

According to Mr. Pagon, the review of the Consumer Complaint #93105 was documented by the aforementioned internal e-mail from Duen Pagon to Bisi Oloruntoba. The referenced internal e-mail noted that the production and quality records were pulled for review. Results and summation of the e-mail reads in part as follows:

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*** "Subject: Rodent in Can

1. Diet Pepsi was produced in 36pk only from 10:59am -15:33pm (filler)
2. [REDACTED] of product was produced
3. Production downtime during 13:00-14:00 hour was 6 minutes 3 min for wrap feed issue at the [REDACTED] packer and another 3mins for open cases at the palletizer. Line efficiency was [REDACTED]

(b)(4)

Production Downtime during the 14:00-15:00 hour was 1 minute from a filler in-feed jam. Line efficiency for this hour was [REDACTED]

(b)(4)

Additionally, I contacted [REDACTED] our pest control agents to see if any rodent activity was noticed during the time of the customer complaint or since then. [REDACTED] does the weekly inspections, reported that there were no rodent activity in or outside the building"***

(b)(4) (b)(6)

We asked to review documents surrounding the other #12 consumer complaints to provide insight into the consumer complaint process from initiation until resolution of the complaint. Ms. Peacock stated that there were no documents on location and that a root cause analysis had not been determined. Ms. Peacock stated that many of the consumer complaints don't have any documentation created at the plant level, especially if a CARPAR is not initiated at the Consumer Affairs Office. When asked what other internal documentation was available at the plant level to show the investigative efforts surrounding any of the consumer complaints identified on the log, she stated that they aren't always written down and most of these are handled via face to face conversation as well as telephone calls amongst the firm's management.

When asked what would trigger a CARPAR being generated at the Consumer Affairs Office, Ms. Peacock responded that this complaint was still at the investigative stage and when additional information is provided by PBG Orlando identifying a root cause then Consumer Affairs or the PBG Orlando QA department will make a determination if a Corrective Action is required. She further stated that the generation of a CARPAR is dependent on the scenario and the communication between the consumer affairs representative and the complainant as well as the plant from which the product originated. I reviewed the document, PBG Corrective Action Program-QRP-001, (Attachment # 9, 3 pages). A copy of this document was requested but refused by Ms. Peacock under the aforementioned authority. Ms. Peacock diagramed the flow process for how consumer complaints are handled on a scrap sheet of paper in her possession, to clarify her point. No copy was provided but was recreated in diary for clarity, (Attachment 10, 1 page).

Recalls-mock recalls are conducted every six months. The plant picks the product to be run through the recall procedure. The firm most recently conducted a mock recall on 4/6/09 and provided for review, documents showing the recall and trace back of the following that reads in part:

*** "Item #90284 5G BIB MTN DEW BAJA BLAST POS for:

- (1) BOL #25548271992 with a ship date of 2/25/2009 at 16:40:14 of [REDACTED] boxes
- (2) BOL #25548273191 with a ship date of 3/06/2009 at 19:15:15 of [REDACTED] boxes

(b)(4)

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(3) BOL #25548273883 with a ship date of 3/13/2009 at 02:15:04 of [redacted] boxes" ***

(b)(4)

Ms. Peacock, Mr. Sullivan, and Mr. Pagon collaboratively denied the recalling of any products in the past 2 years from the PBG-Orlando plant. Ms. Peacock provided the following documents for review and stated, the below documents, are managed by headquarters crisis team contacts Linda Gromadzki and Gina McElgunn:

- (1) Mock Recall Procedures "NCP-009" PBG-Quality Document (QDOC)
- (2) Mock Recall Procedure Reconciliation Worksheet "NCF-005"-This document corresponded with the mock recall conducted on 4/6/09.
- (3) Crisis Management Plan "NCP-007, Rev#3"-This document discusses the actual steps to follow in the event of an actual recall occurring outside of Mock Guidance
- (4) Crisis Management Plan, Appendix Six "NCP-007, Rev#3"
- (5) Crisis Management Quick Book "NCP-008, Rev#3"

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE (RLM)

It was decided that a FDA 483, Inspectional Observations would not be issued after discussion of inspectional findings with FDA district management.

REFUSALS (RLM)

Refusals were encountered only when requesting copies of documents, however the firm did allow viewing of all documents allegedly available at the firm. Copies of documents were refused by Tanya Peacock, HQ Quality Senior Field Representative for PBG International Affairs on behalf of Plant Manager Kevin Sullivan under reported authority of Corporate Legal Counsel, Dave Patrick and VP of World Wide Quality, Gina McElgunn.

GENERAL DISCUSSION WITH MANAGEMENT (RLM)

On 8/04/09 Investigator Racioppi and I observed the following:

- a leaf was observed on the underside of a high density plastic pallet, containing empty cans of "Orange Crush" beverage, in the bulk primary packaging receiving area. The leaf was not in direct contact with any food contact surfaces, but was resting on the section of the pallet that the arms of a pallet jack would slide into, enabling lifting of the pallet. When identified, it was removed by the plant manager and the following explanation given: It must have come in on the pallet. Pallets come from different suppliers. He was unsure of whether they are sanitized or fumigated but indicated he would find out.
- fluid was observed around motors and hydraulics on the underside of the [redacted] system adjacent to door "A4B." The fluid was not in direct contact with any food contact surfaces and was not readily accessible to contact but by crawling underneath the [redacted] [redacted]. When identified, the plant manager stated he would have maintenance address and correct the issue.

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- unused and empty cans and bottles were observed underneath the depalletizer. When identified, the plant manager stated that they would be cleaned up after shut-down of the conveyor line and that this usually occurs at night. Mr. Sullivan further stated that the can line is usually shut down twice per week for external sanitation and on the weekends it depends upon the production schedule.
- three holes (approximately 1½ inches deep by 4 inches wide) were observed in the concrete floor adjacent to the depalletizer. Within the holes, debris was observed. They were not in direct contact with food surfaces. When identified, Mr. Sullivan stated that the holes were the locations of ballard posts that had previously been there but had been removed. We suggested that the holes be cleaned out, debris removed, and back filled with cement. Mr. Sullivan stated that he would ensure that this occurred. On 8/11/09, Mr. Sullivan stated that the holes had been cleaned out and that they had been back filled with cement. I did not confirm this statement.
- empty wooden pallets, used for secondary packaging materials were observed to be stored under the conveyor system used to off-load cans and bottles from the tractor trailers. We suggested to management that they find a new place to store the empty pallets away from the synthetic pallets that are used for the can line and avoid commingling of them. Mr. Sullivan stated that he would ensure the correction was taken care of.
- a broken push broom brush head was observed under the conveyor system. When identified, it was immediately removed, as directed by Mr. Sullivan.
- the hot water spigot in the hand washing sink did not produce hot water upon turning it on and letting it run. I questioned Mr. Sullivan about this and he stated it should be working and asked me if I let it run long enough. On 8/11/09, the hot water spigot in the men's restroom produced hot water upon turning it on. Mr. Sullivan stated that he was not sure why it was not working for me, but that it was working for them, and Mr. Sullivan denied making any repairs or modifications to it when questioned.

On 8/11/09, closeout discussion with PBG management centered on directed discussion points from FDA district management. The following persons were present during this closeout discussion: Ms. Peacock, Mr. Sullivan, Mr. Pagon, and FDA Investigator's Morris and Mundy.

Investigator Mundy and I told Ms. Peacock, Mr. Sullivan, and Mr. Pagon that FLA-DO management encouraged firm to consider adding additional QAP's to address the receiving of primary packaging materials from their suppliers upon receipt of cans at the can line to ensure that no foreign materials are in the cans prior to being introduced into the production line.

Investigator Mundy and I told Ms. Peacock, Mr. Sullivan, and Mr. Pagon that FLA-DO management encouraged firm to consider some type of assurance testing or mock testing to ensure that PBG's QAPs at the [REDACTED] device, the [REDACTED] can rinser, and the experiential foaming process that allegedly occurs, if a foreign object were present in can at time of filling, would indeed be ejected by the firm's [REDACTED] device-based on premature shutoff by the ball check valve in the filler bowl-resulting in an under filled can ultimately being ejected by the [REDACTED] device.

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Ms. Peacock, Mr. Sullivan, and Mr. Pagon acknowledged discussion points and indicated that they would share them with their superiors for review and consideration.

ADDITIONAL INFORMATION (RLM)

Many of the firm's records were reviewed to include the following: production, maintenance, calibration, equipment specifications, crisis management plan, and corporate guidance documents surrounding consumer complaints, certificates of analysis for primary packaging materials (cans), trailer inspection records for outgoing finished product, bills of lading and distribution records associated with the lot in question associated with CC#93105. Copies were requested of many of these documents and all were refused under the aforementioned authority by Ms. Peacock.

SAMPLES COLLECTED (RLM)

There were no official samples collected for laboratory analysis during the course of this inspection. Ms. Peacock directed Mr. Pagon to obtain #4 full cans of Diet Pepsi 12 fl oz and provide them at no cost to FDA for the purposes of a label review. The four cans read in part: *** "Diet Pepsi***0***CAL***CARB***SUG***12 FL OZ***(355ml)***OCT 19 08***0654ES07099***" There was not a receipt for sample or affidavit provided. The cans were transported to the FLA-DO in my possession. I conferred with my supervisor and the district compliance director and was directed to conduct a field examination by opening the cans, observe the contents being poured out, take photographs of the empty cans to document the labels associated with the product to satisfy the requirements of the label review. I completed this task, as directed, on 8/12/09.

VOLUNTARY CORRECTIONS (RLM)

On 8/11/09, Mr. Sullivan, Plant Manager stated that the holes, identified in the floor in the bulk receiving area, had been back filled with cement. Mr. Sullivan also stated that he would ensure that the auto-unloader's motor, identified to be leaking hydraulic fluid, would be repaired and cleaned up, in addition to the loose bottles and can that had fallen below the auto-unloader and wooden pallets that had been stored beneath it.

EXHIBITS COLLECTED

1. PBG Orlando, Can Coding Standards Application, 1 page.
2. Pepsi Bottling Group, Interior Rodent Trap, dated 2/1/09; Exterior Perimeter Rodent Stations, dated 2/1/09; and Fence Line Rodent Stations, dated 2/1/09, 3 pages.
3. Pepsi Bottling Group Orlando, Plant Schematic, 1 page.
4. NLEA Label Review, Diet Pepsi, dated 8/12/09, 12 pages.
5. Officially Sealed Envelope containing CD-R of Photos, mounted on page, 1 page.
6. FACTS Assignment Sheet, Assignment ID: 1073460, Operation ID: 4296803, 1 page
7. Form FDA 482, Notice of Inspection, dated 8/4/09.
8. Form FDA 482, Notice of Inspection, dated 8/10/09.

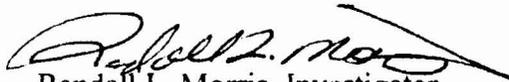
Establishment Inspection Report

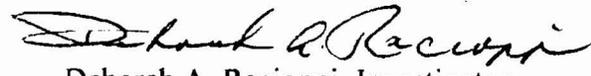
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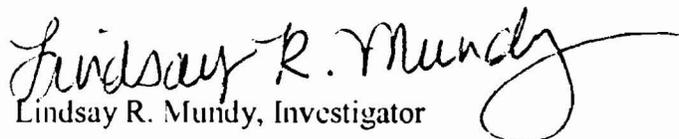
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ATTACHMENTS

1. Pepsi Bottling Group Reported Flow Process for Orlando Plant, Created by Racioppi, 1 page.
2. Duplication in part of PBG/PCNA document showing flow process, Created by RLM, 1 page.
3. Duplication in part of PBG/PCNA document showing water treatment process, Created by RLM, 1 page.
4. Duplication in part of [REDACTED] Air Rinser Spec Sheet, Created by RLM, 2 pages.
5. Duplication in part of PBG/PCNA document showing QAP's and CTS procedures, Created by Mundy, 6 pages. (b)(4)
6. Duplication in part of Task Summary Report, showing maintenance on can line seamer, Created by Mundy, 2 pages.
7. Duplication in part of FILTEC Spec document, showing functional capabilities of [REDACTED] device, Created by RLM, 2 pages. (b)(4)
8. Duplication in part of e-mail, dated Monday July 27, 2009, from Mr. Pagon to Ms. Oloruntoba regarding CC#93105, Created by RLM, 1 page.
9. Duplication in part of Internal Investigation Guidance Document, dated 8/31/001, Created by RLM, 3 pages.
10. Duplication in part of penned diagram by Ms. Peacock, clarifying consumer complaint process, Created by RLM, 1 page.
11. Duplication in part of Reconciliation Exam BOL#19572 information, Created by Mundy, 1 page.
12. Duplication in part of BOL#13159194, BOL# 10855610 from [REDACTED] for primary packaging materials used in production of finished product associated with CC#93105.
13. Duplication in part of BOL showing distribution of finished product associated with CC#93105. (b)(4)


Randall L. Morris, Investigator


Deborah A. Racioppi, Investigator


Lindsay R. Mundy, Investigator