

Peanut Corporation Of America
P.O. Box 448
Highway 62 East Industrial Park
Blakely, GA 31723

11/15/01
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SUMMARY OF FINDINGS

Initial inspection of this peanut processing (blanching and roasting) facility was conducted according to ATL-DO's FY-2002 Work Plans under C.P. 7303.803, Domestic Food Safety Program, and followed up disposition of a lot of shelled peanuts that initially failed the Peanut Marketing Agreement regarding Aflatoxin content per C.P. 7307.001.

Prior to February 2001, this firm processed (blanched, roasted, and packed) peanuts under the name of Casey's Food Products, Inc. In February 2001 the firm, labels and Casey's brand name were sold to Mr. Stewart G. Parnell of Lynchburg, VA. The firm continues to roast and pack Peanuts and shelled nut mixtures under the Casey's label in various sizes of laminated cans, fiber body with a metal end and closed with a foil seal, and glass jars, and 25, 30, & 50 pound bags.

During the inspection, the firm was dry roasting peanuts in 19 OZ. glass jars closed with metal screw lids for (b)(4) stores, one of its two largest customers, the other being the United States Department of Agriculture's Food for Help Programs. There was no USDA Inspector on hand during the inspection, since USDA products were not being produced.

The inspection found a (b)(4) lb. lot of Runner Peanuts that failed USDA's Peanut Marketing Agreement regarding Aflatoxin content was initially reconditioned by the firm and was subsequently sent to a (b)(4) blanching facility for further reconditioning. The lot was blanched two times and failed the Aflatoxin test following each blanching operation. Consequently, the lot was sold to (b)(4) as cooked and raw waste, presumably for use as wild bird feed.

Objectionable conditions observed included ill-repaired equipment, gaps or spaces between an unloading door seal and a semi-trailer that could permit pest ingress into the plant, and webbing and several dead beetles on several multi-ply paper bags of Sunflower Kernels stored on a pallet in the raw material storage warehouse.

Review of the firm's pest control program disclosed (b)(4) (1.68% dicarboximide and 0.700% Piperonyl Butoxide), an insecticide, was applied in fog form in the kitchen, production, and warehouse areas of the plant. The product's labeling indicated that after spraying, all exposed equipment that handled food must be washed with an effective cleaning compound and rinsed with potable water. Management reported it was not aware of labeling changes made by the insecticide manufacturer and had not known that exposed equipment was to be washed and rinsed following application of this product through the firm's (b)(4) Foggers.

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Management reported that most of its food handling equipment was covered except short sections of conveyors, bucket elevators, and temporary holding bins. Reportedly, these pieces of equipment were spatially separated from foggers and were not fully exposed to the insecticide fog, which further limited exposure of food contact surfaces. Since the plant had not been fogged recently, finished product potentially exposed to insecticides could not be identified.

Prior to terminating the inspection, samples 81131 and 81132, 9 oz. cans of oil roasted Party Peanuts and 19 oz. glass jars of salted dry roasted peanuts, respectively, were collected according ATL-DO's FY-2002 Mycotoxin Assignment under C.P. 7307.001.

Management expressed concern over inspectional findings and promised correction of all objectionable conditions. Reportedly, use (b)(4) had been discontinued and the firm had contacted a supplier to identify an insecticide that could be safely applied as a fog in their plant without contaminating product contact surfaces of its food handling equipment.

HISTORY OF BUSINESS

Mr. Raymond Kimbrel, Plant Manager, primarily supplied the History of Business information with Ms. Peggy Harper providing the date the corporation changed its name, inter-state distribution information, and information on the disposition of Peanut Lot No.

(b)(4) 404.

Mr. Raymond Kimbrel, Plant Manager, reported the firm operated as Casey's Food Products, Inc., until February 2001. Mr. Stewart G. Parnell of Lynchburg, VA purchased the firm from Mr. John S. Bailey, former President of Casey's Food Products, Inc. According to Ms. Harper, the change in the corporation's name was officially registered with Georgia Secretary of State as Peanut Corporation Of America on February 28, 2001. Mr. Stewart G. Parnell was identified as President of the corporation. According to Mr. Kimbrel and Ms. Harper, Mr. David Royster III is presumed to be associated with the corporation but his title and responsibilities were unknown by local management. Reportedly, Mr. Royster had visited the firm at least once in the last two years.

When asked about subsidiary or related firms, Mr. Kimbrel reported that Mr. Parnell owns a peanut blanching facility (b)(4). According to Mr. Parnell's business card, Exhibit 1, Peanut Corporation of America's corporate office is located at 2121 Wiggington Road, Lynchburg, VA 24502. The corporation has plants at Blakely, GA 229-723-3411 and Suffolk, VA 757-539-0221. Mr. Parnell verbally confirmed via telephone that Peanut Corporation of America owned (b)(4) (b)(4) and Peanut Corporation of America, Blakely, GA. According to

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Mr. Parnell, the corporate headquarters is located 2121 Wiggington Road, Lynchburg, VA 24502.

This firm blanches and or produces dry and oil roasted peanuts and or nut mixtures. Roasted nuts are packed under the (b)(4) label in ¼ oz. and 3.75 oz. foil bags, 7.25 Oz., 16 Oz., and 19 Oz. glass jars, 8 Oz., 9 Oz., 12 Oz., and 3.75 lb. laminated cans, and 25, 30, and 50 lb. bags.

Reportedly, the firm operates from 7:00 AM through 6:00 PM Monday through Friday. Major maintenance is performed when necessary on Saturdays when the plant is not in operation.

According to Mr. Kimbrel, the Georgia Department of Agriculture's Consumer Protection Division, United States Department of Agriculture, and the U.S. Food & Drug Administration inspects the facility. The United States Department of Agriculture, USDA, is one of the firm's largest customers. The firm produces roasted nuts for distribution under USDA's Domestic Food Assistance Programs. When product is being manufactured under USDA's contract, USDA's own inspectors supervise the production of those products and collect samples as specified by the contract. Since no USDA product was being produced during the inspection, no USDA officials were on hand.

Ms. Harper reported the firm's largest customers include USDA, (b)(4) (b)(4) and institutions such as the (b)(4). The firm's products are shipped nationwide usually via common carrier per customer's own arrangements. According to Ms. Harper, (b)(4) of the firm's production is shipped in interstate commerce.

This was the initial inspection of the firm under current ownership.

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITY

On arrival at the firm, we met Ms. Peggy Harper, Office Manager, and asked to see the owner, operator, or the person in charge. Ms. Harper reported that Mr. Stewart G. Parnell, the new President and owner, had left about one-half an hour earlier on his return to Lynchburg, VA. Reportedly, during Mr. Parnell's absence, Mr. Raymond Kimbrel, Plant Manager, was the most responsible individual at the firm. Ms. Harper summoned Mr. Kimbrel and explained that FDA Investigators were waiting in the office to see him. Mr. Kimbrel arrived shortly and introduced himself as Plant Manager. He stated he was in charge of all operations during the absence of the firm's President, Mr. Stewart Parnell who had departed the firm immediately prior to our arrival. He said Mr. Parnell had planned to call on customers on his return to Virginia and was approximately one half an hour away from the firm and could be recalled if necessary. We reported that we would

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be making a routine inspection and in addition, we wanted to determine the disposition of a blanched peanut Lot (b)(4) 404 that had failed the Peanut Marketing Agreement due to an Aflatoxin level of 71 ppb.

At that point, credentials were presented to and FDA-482, Notice of Inspection, was issued Mr. Raymond Kimbrel, Plant Manager. The form, Resources for FDA Regulated Businesses, was also given to Mr. Kimbrel. Mr. Kimbrel obtained information on Lot (b)(4) 404 and asked Ms. Harper to obtain the firm's records on the lot in question while the inspection was in progress.

Mr. Kimbrel provided history of business and occasionally called on Ms. Harper to provide information on distribution of finished product and volume of product shipped in interstate commerce. Mr. Kimbrel provided inspectional accompaniment, identified manufacturing equipment and explained processes, and answered all questions asked of him. Mr. Kimbrel was observed to take notes during our inspection and later indicated he had taken his own notes identifying equipment that had been repaired with duct or cellophane tape and the location of spaces that could permit pest entry into the plant. He was observed issuing instructions to various employees in the firm's office, kitchen, production areas, and shipping warehouse whom immediately obeyed without question.

Mr. Kimbrel identified and provided copies of records covering interstate shipments the firm had made from finished lots of roasted peanuts that were sampled during the inspection. He also read and affirmed an Affidavit, FDA-463a, covering collection of samples 81131 and 81132.

Upon completion of the inspection FDA-483, Inspectional Observations, and FDA-484, Receipt for Samples, were issued to and discussed with Mr. Kimbrel who acted as spokesman for the corporation. Mr. Kimbrel verbally promised correction of all objectionable conditions.

Ms. Peggy Harper, Office Manager, was met on arrival at the firm and identified Mr. Raymond Kimbrel, Plant Manager, as the most responsible individual at the firm during the absence of its President, Mr. Stewart G. Parnell. Ms. Harper provided the date the firm's name was changed with the Georgia Secretary of State, records covering the firm's attempt to recondition blanched peanut lot (b)(4) 404 and its ultimate disposition, and prepared an invoice billing the cost of samples collected during the inspection.

Prior to completion of the inspection, Mr. Stewart G. Parnell, President, telephoned the firm and was informed of our inspection. Ms. Harper reported that he wanted to talk to one of the FDA people. Investigator Brogden spoke to Mr. Parnell who wanted to know how the inspection was progressing. Mr. Parnell was told that an Inspectional Observations Report, FDA-483, containing several objectionable conditions would be left

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with Mr. Kimbrel. Mr. Parnell was told our report would say that equipment was ill repaired due to the widespread use of duct or cellophane tape, pests could enter the plant through spaces between the northeast door seal and a semi-trailer, and webbing and two dead beetles were found on several bags of Sunflower Kernels stored in the warehouse. Mr. Parnell said it was a good thing the inspection had not been made a couple of months earlier because most of the tape had been removed. He said tape would be removed from equipment and repairs would be made. Mr. Parnell said he had observed the Sunflower Kernels while he was at the firm and had thought they should look at them and possibly discard them because of their age. Mr. Parnell was told no evidence of an active insect problem was observed but plant officials had been shown the webbing and dead beetles. He said they would examine the product before attempting to use it and he thought it would possibly be discarded due to its age.

Mr. Parnell was told that we had reviewed the firm's (b)(4) labeling and it appeared that it was possibly being misused. He was told that (b)(4) labeling indicated that contact surfaces of food handling equipment should be washed with a suitable cleaning compound and rinsed with potable water after it was applied. He said it had been about two weeks since (b)(4) had been used in the plant. He said it appeared that the product's labeling had been changed and they had not been aware of the change. Mr. Parnell said Mr. Kimbrel had discontinued the use of (b)(4) and would check with their supplier to obtain a material that was suited to fogging a food manufacturing facility when it was not operating.

Mr. Parnell said his firm was inspected by USDA and wanted to assure us that he wanted his firm to be in compliance with the F,D, & C Act. He said he had many years' experience in the peanut industry and we should telephone him directly should we have any concerns or questions.

Mr. James Tanner, Sanitation Supervisor, identified insecticides that were used in and on the grounds around the plant. He described how they were applied and provided the frequency of application. When questioned about the use of (b)(4) Mr. Tanner said their supplier had assured them it was suitable for use in the plant before they began using it. He said the labeling on containers on hand appeared to have changed after they started using the product and they had not discovered the change. He said USDA knew it was being used and had not objected to the use of this product. Reportedly, it had last been used to control an isolated insect problem they had in their oil stock storage area.

Mr. Henry Mills, Shipping Supervisor, identified finished roasted peanut lots that were available for sampling and broke these lots down so that representative samples could be collected. He also identified and provided a copy of a picking ticket covering the interstate shipment of a portion of lots sampled under collection report numbers 81131 and 81132. Refer to ATTACHMENTS for copies of these collection reports.

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GUARANTEES AND LABELING AGREEMENTS

Guarantees and labeling agreements were not covered during this inspection.

TRAINING PROGRAM

The majority of the firm's employees receive on the job training. Reportedly, the firm's Sanitation Supervisor has taken a pesticide application course that allows him to use and purchase insecticides used by the firm. Specifics of the course were not obtained.

RAW MATERIALS AND COMPONENTS

Raw materials used in the production of the firm's roasted peanuts and nut mixtures consists of Peanut Oil, 50 lb. capacity poly-lined paper bags of (b)(4) 50 lb. multi-plyed paper bags of (b)(4) Honey in five gallon plastic pails, (b)(4) Salt in 80 lb. multi-plyed paper bags, 50-lb. poly lined boxes of (b)(4) Peanut Coating, Sunflower Kernels in 50 lb. multi-plyed paper bags, and red skin or blanched peanuts in poly-lined 2000 lb. capacity nylon tote bags.

The peanuts used to manufacture the firm's finished roasted nut products are purchased under the terms of the Peanut Marketing Agreement that requires a maximum Aflatoxin level of less than 15 parts per billion, ppb, whereas FDA's action level for Aflatoxins is 20 ppb. An Aflatoxin certificate that specifies the Aflatoxin content of the lot accompanies each lot of peanuts the firm purchases. The firm maintains records covering receipt of each raw peanut lot and also maintains records that allow the firm to trace its use in finished peanuts lots and customers that received finished lots.

OPERATIONS AND EQUIPMENT

Red skin or blanched peanuts are purchased in lots of (b)(4) pounds from local peanut shelling or blanching plants. An Aflatoxin certificate that specifies the Aflatoxin content in the referenced lot accompanies each lot of peanuts. The firm maintains records on each peanut lot it purchases and documents the use of the original peanut lot in the firm's finished roasted nut lots.

Peanuts are delivered to the firm in semi-truck trailers that are positioned for unloading at one of several unloading doors in the kitchen portion of the plant, estimated to be approximately (b)(4) feet by (b)(4) feet, where peanuts are received and roasted. Large seals are placed between the trailer and unloading door to prevent pest entry into the firm while product is being unloaded.

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When a trailer is opened for the removal of peanuts, the trailer's door can not be closed until the trailer is moved away from the exterior of the unloading door. The top portion of the seal described above prevents the door from closing. Peanuts are usually received in poly-lined 2000 lb. capacity nylon tote bags. A lot of peanuts, consisting of (b)(4) to (b)(4) lbs. of peanuts can be roasted during a normal day's production; however, some lots may be roasted over a two-day period. While the lot is being roasted, the trailer door remains open but the kitchen loading door can be closed over night. Spaces that could permit pest entry into the building were observed between the trailer and the unloading door seal.

During the current inspection, the firm was dry roasting blanched peanuts and was packing them into 19 OZ. glass jars closed with metal screw lids. The manufacturing process commenced with a fork lift removing poly-lined 2000 lb. nylon tote bags of blanched peanuts from a semi-truck trailer positioned against the northeast unloading door. Tote bags of peanuts were suspended from a rack above a metal dump bin and were allowed to gravity feed from the bag into the bin. The bin discharged into a vertical bucket elevator that conveyed the peanuts into an estimated (b)(4) lb. capacity metal holding bin. Blanched peanuts gravity fed out of the holding bin on to a short stainless steel vibratory conveyor that discharged blanched peanuts into a declined stainless steel tumble drum. Duct tape was observed at the juncture of the bottom of the holding bin and a metal chute supplying blanched peanuts to the vibratory conveyor. A piece of cardboard that was in contact with blanched peanuts was inserted into the end of the vibratory conveyor and between the chute discharging peanuts onto the conveyor.

Water was sprayed onto peanuts as they entered the tumble drum in preparation for coating with salt and a (b)(4) peanut coating supplied by a stainless steel salt funnel that discharged coating into the bottom one-third of the tumble drum. Bulging duct tape was observed over and around the sight glass on the Salt Funnel. Salted, coated, blanched peanuts exited the tumble drum onto a reciprocating belt conveyor that spread coated blanched peanuts on a stainless steel belt entering a dry roaster estimated to be (b)(4) feet long. The first zone of the roaster has a maximum temperature of (b)(4) degrees F and reached a maximum of (b)(4) degrees F in the second zone. Roasting time is estimated to be approximately (b)(4) minutes.

Roasted peanuts are discharged from the roaster onto a vibratory stainless steel conveyor, that also removes excess or loose coating, which discharges into a vertical bucket elevator. The vertical bucket elevator conveys roasted peanuts from the kitchen into the production area, also estimated to be approximately (b)(4) feet by (b)(4) feet, which is separated by a concrete block wall from the kitchen. The vertical bucket elevator discharges roasted peanuts into an estimated (b)(4) lb. capacity overhead stainless steel holding bin.

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Glass jars received in cardboard cases on wood pallets are manually de-palletized and are placed on a belt conveyor leading to an air washer, an enclosed circular device that inverts jars and blows compressed air in and vacuums out the interior of each jar. This device was cleaning (b)(4) OZ. jars per minute. More than 155 jars were cursory examined as they exited the air wash machine and a fiber like object was on the outside rim of one jar, that was removed by Mr. Kimbrel before the jar was filled.

A stainless steel tumble filler fills 19 OZ. glass jars with roasted peanuts. A belt conveyor conveys empty jars into the right side of the filler. A stainless steel vibratory conveyor, that removes loose coating from the peanut stream, supplies roasted peanuts to the left side of the tumble filler. Torn duct tape with threads looking like webbing was partially covering a hole on the exit end of the tumble filler. Too, cellophane tape had been applied around the filler at the juncture of the body and exit and entrance ends of the filler.

Filled glass jars of roasted peanuts are checked for proper fill weights (b)(4) grams to (b)(4) grams, when the line starts up and at (b)(4) minute intervals. Employees working on the filling line visually examine jars for under fill levels. Jars suspected of being under filled are removed from the line and are individually check weighed. Should a jar contain less than (b)(4) grams, roasted nuts are manually added to the jar until the proper weight is obtained and the jar is manually placed on the packing line. The filler is also checked to determine why jars are not being properly filled. Under filled jars usually were caused by a low peanut volume in the filler.

Filled jars are conveyed past a metal detector that is checked before the line is started up. To perform the check, a metal object is placed in a jar filled with peanuts and is passed by the metal detector. If the jar is kicked off the conveyor belt, the test is successful. Checks are also made in the afternoon and or when the line is down for an extended period of time.

Employees placed metal screw lids on top of each filled jar they passed the metal detector. Jars were conveyed to a lid-closing machine where a vacuum of approximately (b)(4) inches of Mercury was pulled on each jar prior to closing machine tightening the lid on each jar. A block of wood between the lid closing machine and the belt conveying filled jars to the lid closing was held in place with duct tape. Too, a piece of cardboard had been duct taped to the lid-closing machine to shield employees from flying glass from jars that shattered when vacuums were being pulled on them. This piece of cardboard contained a hole approximately 2 inches by 6 inches.

Jars were conveyed past an ink jet printer that applied the lot number, actually an expiration date, month, and day, and year, one year in advance of the date of manufacture, on the side of each jar lid. The lot number 11/15/02 was being applied to

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the sides of lids applied to (b)(4) 19 OZ. jars of (b)(4) Salted Dry Roasted peanuts packed on November 15, 2001. Refer to Exhibit 2 for the referenced product's label.

Closed glass jars of roasted peanuts were conveyed to the labeling machine where a label was applied to each jar, Exhibit 2. Labeled (b)(4) 19 OZ. jars of (b)(4) Salted Dry Roasted Peanuts were conveyed to the packing station where 12/19 OZ. jars of product were packed into the original cardboard shipping case. The exterior of each case was ink jet labeled with the amount of product, 12/19 OZ, a product number, i.e. 43112, and Expiration Date, 11/15/02, and product description, i.e. D/R Salted Peanuts.

Cases of dry roasted peanuts were stacked on wood pallets. When the appropriate number of cases had been stacked on a pallet, a multiple copy pre-numbered tag that identified the product, pallet number, and lot number and expiration date was applied to the pallet. Pallets of finished product are held in the firm's warehouse until they are shipped to the consignee. When the pallet is pulled for shipping, a copy of the pre-numbered pallet tag is removed and is attached to the firm's shipping records. Since the firm's production records identify the number of each pallet in the shipment, the firm is able to determine the portion of the lot that was supplied to each consignee.

When the inspection commenced, the firm's oil roaster was being serviced. Oil had been removed from the oil roaster and was being filtered to remove peanut particles and excess fatty acids. The oil roaster was started up before the inspection was concluded but the oil roasting line was not covered.

The peanut blanching section of the plant was not operating during this inspection. Mr. Kimbrel reported it had not been used for some time because their equipment was dated and in need of repair and replacement. He speculated this operation might be discontinued and equipment removed to provide space for other operations. This operation was not covered since it was not operational and could possibly be eliminated at some point in the immediate future.

The firm is responsible for performing insect and rodent control functions inside the plant. Glue boards inside approximately 6 inches to 8 inch lengths of 2 inch diameter PVC pipe were located on each side of unloading and entry doors and along interior walls. Glue boards are checked daily for trapped rodents and records are reportedly maintained identifying the areas where rodents are found. According to management, no rodent activity had been observed in recent weeks. No rodents were observed on any of the glue boards currently in use.

Insect control involves crack and crevice applications at (b)(4) day to (b)(4) day intervals of (b)(4) Active Ingredient 11.8% dimethyl cyclopropanecarboxylate, made by (b)(4). This material is applied via a hand held sprayer in a

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wet spray at the interior junctures of floors and walls. Crack and crevice treatments are applied when the plant is not operating.

Reportedly, the firm has a (b)(4) fogging machine located on the east wall of the kitchen, (b)(4) in the production area, (b)(4) in the blanching section, and (b)(4) in the warehouse that fog these areas with (b)(4) an insecticide manufactured (b)(4) (b)(4). Active ingredients include 1.168% N Octyl bicycloheptene dicarboximide, 0.700% Piperonyl butoxide, technical, 0.025% and Other Isomers, and 0.325% d-trans-Chrysanthemum monocarboxylic acid ester of d-2-allyl-4-hydroxy-3-methyl-2-cyclopenten-1-one, Exhibit 4. Reportedly, the plant is fogged during the night when the plant is not operating and no nuts remains in processing equipment. Reportedly, this material is used to control flying insects.

Mr. James Tanner, Sanitation Supervisor, was interviewed concerning the firm's pest control activities. Reportedly, (b)(4) applications are made daily when needed and are approximately (b)(4) long. A cursory review of (b)(4) labeling disclosed that all equipment, benches, shelving, etc., where exposed food will be handled must be washed with an effective cleaning compound and rinsed with potable water, Exhibit 4. When asked if exposed equipment was covered prior to the plant being fogged with (b)(4) Mr. Tanner said they did not know that equipment had to be covered. When this portion of the label was pointed out to Mr. Tanner, he said the label had obviously been changed without him being aware of the change. He pointed out that most of their equipment was covered; however, there were open dump hoppers and short sections of conveyor belts that were not covered when the plant was fogged. Mr. Tanner said there was (b)(4) fogging machine per area and it was possible that the fog would not have contaminated exposed surfaces due to the direction of the fog and the location of the equipment in question. Reportedly, the warehouse where oil stock was stored was the last area where this material was significantly used. According to Mr. Tanner, an insect problem was found sometime in October, 2001 in their peanut oil stock. This area was fogged to control the insect problem and the oil stock had been sold and removed from their warehouse. No live insects were observed in the plant.

According to Mr. Tanner, (b)(4) provides rodent control outside of the plant. Rodent bait boxes have been placed along the exterior walls of the firm and along the perimeter of the firm's property. According to management, (b)(4) has placed a paraffin type bait bar inside each of the exterior bait boxes.

No recent rodent evidence was observed during this inspection. No rodent burrows or other rodent evidence was observed outside of the plant.

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MANUFACTURING CODES

The firm applies an expiration code to each container of finished product that consists of a total of six digits, two digits for the month, day of the month, and year. This code is one year in advance of the date of manufacture. During the inspection, individual product containers and the exteriors of those shipping cases were identified with an expiration date of 11/15/02. This code identifies the date of manufacture November 15, 2001 and the shelf life of the product, November 15, 2002, one year in advance of the date of manufacture.

DISPOSITION OF BLANCHED PEANUT LOT No. BM 1404

After the inspection began, Ms. Peggy Harper, Office Manager, was advised that we wanted to know the disposition of (b)(4) pounds of Blanched Runner Peanuts, Lot (b)(4) 1404, that contained 71 ppb (parts per billion) Aflatoxins, according to USDA's Certificate of Analysis B 0100758 dated January 17, 2001, Exhibit No.5A. Exhibit 5B is a copy of the firm's history and disposition of the suspect lot.

According to Ms. Harper, Office Manager, Lot (b)(4) 1404 originally consisted of (b)(4) pounds. The lot was blanched/reconditioned by (b)(4) during the period of 1/8-10/01 per firm's Production Record Lot No. (b)(4), Exhibit 6. (b)(4) initial reconditioning effort produced (b)(4) pounds of product packed under Lot (b)(4) 1404B, (b)(4) pounds of rejects (oil stock), and (b)(4) pounds of shrinkage, loss of moisture and fines during drying and blanching. Reportedly, the lot failed to meet grade and Aflatoxin requirements and was reprocessed or reworked beginning on 1/24/01. The second effort to recondition the lot, Lot (b)(4) 404-B produced (b)(4) pounds of product, (b)(4) pounds of rejects, and (b)(4) pounds of shrinkage, Exhibit 7.

The lot failed to meet grade and marketing requirements and was subsequently shipped to (b)(4) under the firm's Straight Bill of Lading, Shipper No. 3917, dated 2/16/01, Exhibit 8, for reconditioning. According to (b)(4) Incoming Production Report dated 2/16/01, Exhibit 9A, (b)(4) pounds of Blanched Splits were received in (b)(4) notes. (b)(4) Finished Product Report dated 2/28/01 documents their blanching of the suspect lot under their lot number 14120-99 which produced (b)(4) pounds of product, (b)(4) pounds of oil stock, and (b)(4) pounds of shrinkage, Exhibit 9A. (b)(4) Invoice No. 901307 dated 2/28/01 documents (b)(4) initial reconditioning effort, Exhibit 9C.

Lot 14120 was sampled and the sample was submitted to USDA's Blakely, GA laboratory for Aflatoxin Analysis. (b)(4) Certificate of Analysis No. B 0101369 dated 3/01/01, Exhibit 9B, reports the lot failed to meet the requirements of the Marketing Agreement since it contained 30 ppb Aflatoxins.

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According to the lot summary, Exhibit 5B, (b)(4) reconditioned Lot 14120-99 a second time and it again failed to meet Aflatoxin requirements. (b)(4) Bill of Lading No. 901145 dated 4/4/01, Exhibit 10, documents the return of (b)(4) pounds of product under Lot No. 14270-99 and 4 burlap bags of oil stock totaling (b)(4) pounds. (b)(4) (b)(4) Receiving Log dated 4/4/01, Exhibit 11, documents receipt of (b)(4) pounds of blanched splits that failed to meet grade and (b)(4) pounds of oil stock.

Ms. Harper said the peanuts received from (b)(4) plus the rejects from their (b)(4) and (b)(4) first and second blanching efforts, totaling (b)(4) pounds, were sold to (b)(4) (b)(4) Exhibits 12A-12E. The known shrinkage from reconditioning of the lot (b)(4) plus the oil stock retained by (b)(4) pounds) when added to the (b)(4) pounds sold to (b)(4) accounts for (b)(4) pounds in the original lot.

According to Ms. Harper, the lot in question was shipped to (b)(4) Exhibit 12 D. Ms. Harper said the buyer knew the product had failed to meet grade and marketing requirements. Since the firm knew the consignee was a bird feed manufacturer, it was assumed the product in question had been used in the preparation of a bird feed product.

LABEL REVIEW

A cursory exam of two of the firm's product labels, "3 OZS. MORE BONUS 19!! SALTED PEANUTS BONUS PAK DRY ROASTED (b)(4) PEANUTS *** NET WT. 19 OZ (539g) ***", Exhibit 2, and (b)(4) UNSALTED PEANUTS NET WT. 12. OZ. (340g)***", Exhibit 3, revealed no obvious deficiencies regarding general and nutritional labeling requirements. Management was advised that the firm would be notified should a review by ATL-DO's Compliance Branch find deficiencies in their labels.

OBJECTIONABLE CONDITIONS

Objection conditions will be reported here in the order they were listed on the Inspectional Observations Report, FDA-483, issued to Mr. Raymond Kimbrel, Plant Manager, upon completion of the inspection.

Item 1: Ill-repaired equipment was observed as follows:

- A. Duct tape wrapped around juncture of holding bin and metal chute supplying blanched peanuts to tumble drum.
- B. Cardboard inserted between chute and vibratory conveyor discharging blanched peanuts into tumble drum.
- C. Duct wrapped around and partially covered sight glass on Salt Funnel.

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- D. Torn duct tape with dangling threads partially covered opening on exit end of tumble filler on dry roast line.
- E. Cellophane tape wrapped around the juncture of the entrance and exit ends of the tumble filler on the dry roast line.
- F. Duct tape was wrapped around the chute from the lid machine extending to the capping machine.

Mr. Kimbrel was advised that the duct tape on the sight glass on the Salt Funnel was bulged indicating salt or peanut seasoning used to coat dry roasted peanuts might have gotten between the tape layers. He was advised this condition if uncorrected could possibly become a harborage site for insects. He was also advised the cardboard found between the metal chute and vibratory conveyor discharging peanuts into the tumble filler was in direct contact with the peanut stream.

Mr. Kimbrel was told that we saw a couple of other areas where duct tape and other objects had been applied to production equipment. For example, duct tape was used to secure a block of wood used as a spacer between the filled jar conveyor line and the capping machine. A piece of cardboard with a hole about 2 inches by 6 inches was taped on the side of the capping machine separating the capping machine from the ink jet printer. Reportedly, this piece of cardboard was used to shield workers from flying glass when jars broke on the capping machine.

Item # 2: Gaps were found between loading door seals and a trailer supplying blanched peanuts for roasting operations. An estimated 3-inch by 7 foot space was observed between the top of the trailer and the seal at the top of the door. An estimated 1.25-inch by 7 foot vertical space was observed between the seal on the west side of the northeast loading door and the west wall of the trailer. A space approximately 18 inches wide by 6 feet long was observed between the floor of the trailer and the floor of the northeast loading door.

Mr. Kimbrel was told that the statement above should have said that when the trailer and loading doors were both open, the described spaces or gaps led directly to the outside and could have permitted pests to enter the kitchen. He said he was present and observed the spaces and understood why they were listed on our written report.

Item # 3: Webbing was found on two bags of Sunflower Kernels stored on a pallet in the ingredient storage area of the warehouse. Two dead beetles were also observed on the exteriors of 3 of 10 bags on this pallet.

Before the inspection was completed, Mr. Stewart G. Parnell, telephoned the firm and asked to speak to one of the FDA inspectors. CSO Brogden spoke to Mr. Parnell. Mr. Parnell inquired about our inspectional findings and asked if the firm would be given a

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report when the inspection was completed. Mr. Parnell was told that we would issue the original FDA-483, Inspectional Observations Report, to Mr. Kimbrel. He was advised this report would describe conditions that in our opinion were objectionable and if uncorrected could result in the production of an adulterated or misbranded food product. The conditions reported above were verbally described to Mr. Parnell. When advised of the numerous duct and or cellophane tape repairs made to production equipment, Mr. Parnell said we should have seen all of the tape they pulled off equipment after he purchased the firm. Mr. Parnell said USDA permitted the firm to apply tape to equipment if it was dated and was replaced weekly. He was advised that FDA had at one time recognized that practice but our experience indicated a firm had fewer sanitation problems when equipment was expediently repaired rather than temporarily repaired with tape that became permanent. He stated that he wanted to comply with all of FDA's requirements and equipment would be repaired so that tape was no longer needed on their equipment.

When Mr. Parnell was told about webbing and dead beetles found on several bags of Sunflower Kernels stored on a pallet in their warehouse, he said he had looked at the Sunflower Kernels during his visit and debated whether to have them destroyed. He said he would tell Mr. Kimbrel to pull the Sunflower Kernels and examine them and to destroy them if there was any doubt. Mr. Parnell asked if we had observed any live beetles on the Sunflower Kernels. He was told that we had checked the sewn seams of the bags and had not observed any live beetles, no insect drilled holes in the bags, or any current insect evidence.

Mr. Parnell was also told the firm was using (b)(4) an insecticide applied as a fog to control flying insects in the plant. The product's labeling recommended that an effective cleaning compound be used to wash all contact exposed surfaces of food handling equipment followed by rinsing with potable water after (b)(4) had been applied. Mr. Parnell was told that employees had said they had not washed and rinsed the exposed surfaces of food handling equipment after this material had been applied. He voiced concern and said they had been told the product could be safely used in their peanut roasting plant before they purchased it. He indicated the product's labeling must have been changed without the firm being aware of the change. Reportedly, the product had last been used about two weeks ago. Mr. Parnell said USDA had not objected to their use of (b)(4) but they would cease use of this product until their supplier could provide assurance that the product could be safely used as applied in their plant or another acceptable material could be found.

Mr. Parnell said USDA was one of his largest customers and he wanted to be in compliance with all the laws and regulations of all regulatory agencies inspecting his firm. He said he should be telephoned at his Lynchburg, VA office if we had questions or concerns we needed to discuss with him. Mr. Parnell was told that Mr. Raymond Kimbrel

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had accompanied us during the inspection and was aware of the objections described above was observed to take notes concerning these observations.

SAMPLES COLLECTED

Two samples, 81131 and 81132, 9 OZ. cans of (b)(4) Party Peanuts and (b)(4) 9 OZ. Bonus Pak Salted Dry Roasted Peanuts, respectively, were collected for Aflatoxin Analysis. These samples were collected according to ATL-DO's FY-2002 Mycotoxin Sample Assignment under C.P. 7307.001. Refer to the ATTACHMENTS section for a copy of these collection reports.

COMPLAINTS

Ms. Harper acknowledged that the firm maintains a complaint file. Although the complaint file was not examined, Ms. Harper reported the firm typically receives about 10 to 15 complaints a year that usually report foreign objects such as rocks or glass. Reportedly, the firm corresponds with the consumer apologizing for the problem and sends the consumer complimentary product.

Reportedly, complaints involving foreign objects are difficult to investigate due to their isolated occurrence. For example, rocks are occasionally found in redskin peanuts since they come from the fields where peanuts are harvested and are usually the same color and size of peanut kernels; therefore, rocks may not be removed by electronic sorting machines.

If the consumer provides the suspect product's lot number, the firm conducts an internal investigation to determine if their production records indicate that glass containers were broken during the production of the lot in question or if other problems were encountered during the production of that lot, i.e. rocks found in the product. Reportedly, most complaints can not be followed up because complainants do not usually provide the lot number of the product involved in the complaint.

If the complainant alleges that the foreign object caused an injury, i.e., broken tooth, the complainant's name and address are provided to their liability insurance company. Their insurance company contacts the consumer and may investigate the complaint.

Reportedly, the firm has not received any recent complaints reporting spoiled product or a food related illness. Ms. Harper recalled the firm had received complaints alleging the product was stale or rancid but reported that had been at least one or two years ago.

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RECALL PROCEDURE

We did not ask to see the firm's Recall Procedure; however, records provided during this inspection indicate that the firm could successfully conduct a recall should the need arise. The firm maintains records covering the receipt of each peanut lot and production records documenting the use of each lot in specific lots of finished product. Shipping records also identify the product, pallet number, and the lot number of each product shipped to each consignee. Should a recall become necessary, the firm knows the amount of product they produced under the suspect lot number and can identify consignees receiving the suspect lots.

PROMOTION AND DISTRIBUTION

According to Ms. Peggy Harper, Office Manager, the firm produces roasted peanuts and nut mixtures for three major customers, namely the United States Department of Agriculture (b)(4) and (b)(4). Roasted peanuts and nut mixtures are also manufactured for other firms and institutions such as the (b)(4) (b)(4) and (b)(4).

Reportedly, (b)(4) of the firm's production is shipped in interstate commerce primarily via common carrier. Product produced under USDA contract is shipped in truck load lots, usually via carriers obtained by the firm such as (b)(4) (b)(4) etc. Customers such as (b)(4) order product in less than truck load lots and normally arrange pick-up by their own carriers.

Although the firm reportedly ships its products nation wide and to Canada, management reported shipments had been made to the states of California, Oklahoma, Missouri, Mississippi, Kentucky, Florida, Virginia, Georgia, and New Jersey.

REFUSALS

No refusals were encountered during this inspection.

DISCUSSION WITH MANAGEMENT

Upon completion of the inspection, a final discussion was held with Mr. Raymond Kimbrel, Plant Manager, representing the corporation. Mr. Kimbrel read, verbally affirmed, and signed an Affidavit, refer to ATTACHMENTS, covering interstate shipments of roasted peanut lots sampled under collection reports 81131 and 81132. Refer to ATTACHMENTS for copies of collection reports. FDA-484, Receipt for Samples, was also issued to and signed by Mr. Kimbrel.

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FDA-483, Inspectional Observations Report, was issued to and discussed with Mr. Kimbrel. While observations on the FDA-483 were being read, Mr. Kimbrel made no comments. When the report was completed, we advised Mr. Kimbrel we observed several other conditions we felt should be brought to his attention since they had not been listed on the FDA-483. He was advised we had observed that a bag of (b)(4) (b)(4) Salt stored on a pallet under a (b)(4) Fogger on the warehouse wall was torn open and exposed part of the contents. Mr. Kimbrel said they had terminated use of their foggers until they could determine that (b)(4) was acceptable for use as a fogging material in a food plant or until an acceptable substitute could be obtained. He said they would secure the bag of salt in question.

Mr. Kimbrel was advised that duct tape and cardboard were found on processing equipment in other areas that were not listed on the FDA-483. For example, a wood block spacer was located between the filled jar conveying line and the jar closing machine and a piece of cardboard was duct taped to the closing machine to shield employees from flying glass when glass jars shattered on the jar closing machine. Mr. Kimbrel said they would make suitable repairs in these areas.

Mr. Kimbrel was also advised that although we did not cover the oil roasting line, we observed that one of several tanks used as a temporary storage site when roasting oil was being filtered remained uncovered when oil had been emptied from the tank. Too, another oil holding tank was equipped with a lid but the lid had been folded on top of itself leaving at least half of the tank of oil uncovered. Grease had been allowed to build up on the exterior of the oil filter casing causing an objectionable appearance. Mr. Kimbrel said the lid on the middle tank of oil would be unfolded so that the top of the tank would be completely covered. He also promised to have a suitable cover placed over the intermediate oil tank. He said a visitor to the plant would not be favorably impressed by the external condition of their oil filter and it would be steam cleaned to remove old oil residues.

Mr. Kimbrel said Mr. Parnell wanted to be in compliance with the requirements of all regulatory agencies, Georgia Department of Agriculture, USDA, and FDA. He said he had taken several pages of notes during our inspection and would discuss his notes and our observations with Mr. Parnell. Mr. Kimbrel said their new President, Mr. Parnell, had not complained about the costs required to repair processing equipment instead of making duct tape repairs. He felt Mr. Parnell would authorize repairs needed to eliminate the need for all of the duct and cellophane tape observed during the current inspection.

Prior to terminating the inspection, Mr. Kimbrel was advised of the regulatory actions that were available to the Agency to obtain compliance with the F, D, & C Act including: Administrative and Warning Letters, seizures, injunctions, and prosecutions. Each of

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these actions was briefly explained to Mr. Kimbrel. At that point, the inspection was terminated.

ATTACHMENTS

Copy of the FDA-482, Notice of Inspection.
 Copy of the FDA-483, Inspectional Observations Report.
 Copy of the FDA-484, Receipt for Samples.
 Copy of the FDA-463a, Affidavit, affirmed by Mr. Raymond Kimbrel, Plant Manager.
 Copy of Collection Report for Sample No. 81131, 9 OZ. Cans of Party Peanuts
 Copy of Collection Report for Sample No. 81132, 19 OZ glass jars of dry roasted salted peanuts.

EXHIBITS

1. Business Card: Stewart G. Parnell, President
2. Label (b)(4) BONUS PAK 19 OZ. SALTED DRY ROASTED PEANUTS
3. Label (b)(4) UNSALTED PEANUTS in 9 OZ cans
4. Photos of labeling on a 5 gallon plastic pail of (b)(4)
- 5A. Copy of Certificate of Analysis B 0100758 dated January 17, 2001
- 5B. Copy of firm's history of Peanut Lot (b)(4) 404
6. Copy of Reconditioning Records for Lot (b)(4) 404 dated 1/8-10/01
7. Copy of Reconditioning Records for Lot (b)(4) 404-B dated 1/24, & 29 & 2/5/01
8. Copy of Straight Bill of Lading Shipper No. 3917 dated 2/16/01
- 9A: Copy of (b)(4) Incoming & Finished Product Report Lot (b)(4) 404-B dated 2/16/01
- 9B: Copy of Certificate of Analysis B 0101369 dated March 01, 2001
- 9C: Copy of (b)(4) Invoice No. 901307 dated 2/28/01
- 10: Copy of (b)(4) Bill of Lading No. 901145 dated 4/4/01
- 11: Copy of (b)(4) Food Products, Inc.'s Receiving Log dated 4/4/01
- 12A: Copy of PCA's Invoice No. 42401 dated 4/3/01
- 12B: Copy of numbered pallet tags of peanuts (waste) sold to (b)(4)
- 12C: Copies of pre-numbered tags on pallets of peanut waste
- 12D: Copy of Peanut Corporation of America's Bill of Lading No. 4028 dated 4/24/01
- 12E: Copy of (b)(4) Scale Ticket, Tag No. 300, dated 4/24/01

Melissa M. Benjamin, # 110
 Microbiologist, SRL

B. Douglas Brogden
 B. Douglas Brogden, # 205
 Investigator, Tifton RP