

Establishment Inspection Report

ConAgra Grocery Products
Sylvester, GA 31791-0585

FEI: 1038538
EI Start: 02.23.2005
EI End: 02.24.2005

SUMMARY

Complaint

The current inspection of this large peanut butter manufacturer was conducted under the Domestic Food Safety Program, CP 7303.803, and in response to several complaints (FACTS Numbers 24675, 25509, 27728, 27977, and 28611, received from 4/16/04 to 12/8/04) including most recently, a written complaint (FACTS Number 29134 dated 1/13/05) from an individual requesting anonymity.

The latter complaint included some specific allegations (microbial problems at the firm in October of 2004, insect infestation, etc.) that in summary allege generally poor in-plant sanitation and maintenance and poor quality program management. To preserve the requested anonymity, the copy of the written complaint received by Tifton RP is not attached to this report, but is submitted to the district under separate cover.

The firm continues to function as the only manufacturer of Peter Pan brand of peanut butter, and one of at least (b)(4) producers of (b)(4) (label) of peanut butter. During this inspection the firm produced Peter Pan Creamy Peanut butter in 18 and 28 oz. plastic jars and in a 6 lb. laminated can. Inspection covered general sanitation and pest control, maintenance of equipment including new equipment installation, complaint handling, and quality control activities including finished product testing and release.

Inspection revealed the following concerns: 2 areas on production lines where filled containers of peanut butter were not completely covered from overhead contamination, an accumulation of spillage and or dust at wall/floor juncture around air handling cabinet in the ingredients room, and a temporary baffle made of cardboard in use on an empty jar line. Insect evidence observed was limited to a single moth flying in the enclosed garage area where bulk trucks of peanuts are pneumatically unloaded. Examination of raw and roasted peanut cleaning, sorting and blanching equipment, including elevator boots and buckets and aspiration collection points and discharges revealed no apparent insect activity. No FDA-483 was issued and the concerns were verbally discussed with management.

During the inspection, covers were placed over the exposed areas on the (b)(4) production lines, and the cardboard baffle was discarded.

Management verbally reported that each day's production is tested in-house for Salmonella and coliforms prior to release of the production for sale. Firm acknowledged that there was some production in October that did not meet product specifications and was put on a Micro hold, and was subsequently destroyed. However, management would not report the exact reason for the hold, nor the amount of product affected.

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The firm did provide a review of micro testing results on 2 dates in October that were reported to be 2 dates on which new (b)(4) (heat exchangers) were placed on line after having been cleaned and sanitized. Tests on both dates were "negative" for Salmonella and coliforms.

Sample 308388, Peter Pan Peter Butter in 18 oz. jars and packaged on 2/24/05, was collected and submitted to SRL for microbial analysis per PAC 03803D.

ADMINISTRATIVE DATA

Inspected firm: ConAgra Grocery Products
Location: 101 S Seabrook Dr
P.O. Box 585
Sylvester, GA 31791-0585
Phone: 229776-8811
FAX:
Mailing address: 101 S Seabrook Dr/Pob 585
Sylvester, GA 31791

Dates of inspection: 2/23/2005, 2/24/2005
Days in the facility: 2
Participants: Jackie M Douglas, Investigator

HISTORY

This firm is part of ConAgra Grocery Products Company, which is a division of ConAgra Foods, Inc. The division office is located in Irvine, CA. ConAgra Foods, Inc. is located in Omaha, NE, and per the Nebraska secretary of State's web posting, is a foreign corporation incorporated in Delaware in 1976, with the registered agent identified as McGrath, North, Mullin, & Kratz, PC, 1601 Dodge Street, Omaha, NE.

The Sylvester, GA firm is reported to be the only facility manufacturing Peter Pan Peanut Butter. The firm also manufactur (b)(4) Peanut Butter, a brand sold by (b)(4) (b)(4) stores. The firm has no FDA regulatory history.

The previous FDA inspection here was 8/4/2000 and was limited to a follow up of 4 ppb aflatoxin B1 found in a surveillance sample of peanut butter. The firm refused to provide review of production and shipping records for the specific lot without a written request. No FDA-483 was issued. Previous

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FDA contact here was an investigation completed 2/14/04 conducted in follow-up to complaint 22892 regarding inaccurate labeling in reduced fat peanut butter. The firm had corrected the labeling declaration on the product.

INTERSTATE COMMERCE

The firm routinely ships in interstate commerce via common carrier, and distributes peanut butter from this location to ConAgra's warehouse distribution locations, the nearest of which are located in Atlanta, GA and Jacksonville, FL. The firm ships some product directly to (b)(4) stores.

JURISDICTION

During this inspection the firm manufactured creamy peanut butter and packaged it under the Peter Pan label in 18 and 28 oz. plastic jars, and a 6 lb. composite can. Refer to Exhibits 4 through 6 for labeling of these products. The firm also packages Peter Pan peanut butter in 12, 40, 48, and 56 oz. plastic jars.

(b)(4) products are packed in 18, 28 and 40 oz. plastic jars only. I did not witness any production of (b)(4) product, nor any reduced fat peanut butter, or non-standardized peanut butter spreads which the firm also produces.

Management reports the firm uses only domestic peanuts in its production of peanut butter products.

RESPONSIBILITY

Upon entering the firm on 2/23/05, I was asked by the receptionist to sign in and to read and sign the attached (see Exhibit 1) Plant Confidentiality Agreement. I advised her I would read it but could not sign it. I read it and asked if I could keep a copy and she agreed.

I asked for the Plant Manager and was directed to Mr. Thomas C. Gentle. Credentials were shown to and the FDA-482, Notice of Inspection (and "Resources for FDA Regulated Businesses" document) issued to Mr. Gentle. Present also at this time were Mr. Michael J. Matis, Quality Assurance Manager, and Mr. Rick A. Young, Maintenance and Sanitation Manager. These 3 individuals accompanied throughout the inspection on 2/23. On 2/24, Messrs. Gentle and Matis accompanied. Mr. Matis and Mr. Gentle accompanied during sample collection on 2/24/05, and the FDA-484, Receipt for Samples, was issued to and signed by Mr. Gentle.

The current Food Security Guidance document was provided to Mr. Gentle, and I inquired as to the firm's registration status under the bio-terrorism rule. Mr. Matis advised the firm was registered and that had been handled by the firm's corporate office.

I explained to Messrs. Gentle, Matis and Young that this was a GMP inspection precipitated by recent complaints and I provided some background information to them. Refer to the heading

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Complaints/ Product Defects for the content of this discussion and additional information related to the firm's handling of complaints.

Messrs. Gentle and Matis provided information related to complaint handling, history of business, chain of command, and general processing operations. Mr. Matis answered questions related to the firm's quality control operations. Mr. Young answered questions related to equipment operations, maintenance, and sanitation and pest control activities.

On 2/23/05, Mr. Matis cited corporate policy in initially delaying review of written quality procedures related to microbial testing of peanut butter. He said he would have to check with the firm's corporate offices before allowing it. On 2/24, Mr. Matis provided a verbal overview of the firm's microbial testing program and showed to me test summaries on finished product. He reported having obtained permission to do so from the firm's legal counsel, (b)(4). (b)(4) Mr. Matis declined to answer a question as to whether or not aflatoxin test results posted on lot identifications of raw peanut bins were the results from in-house tests or from vendor/USDA supplied certificates.

Mr. Matis reports directly to Mr. Gentle. Mr. Gentle is the most responsible person present here on a day to day basis. Mr. Gentle reports to Mr. Joe McSherry (Omaha NE), Director of Operations for the ConAgra Grocery Products Division. Mr. McSherry, in turn reports to Mr. Greg Smith, Vice President of Operations, and Mr. Smith to Mr. Dean Hollis, President of the Grocery Products Division. Messrs. Hollis and Smith are located at Irvine, CA. (PO Box 57079, Irvine, CA 92619-7078). Mr. Bruce Rhode was identified as president of ConAgra Foods of Omaha, NE.

MANUFACTURING CODES

The code in use is best explained through an example, as follows:

Given the following code of "21115055 00 1037A BEST BY AUG242006", the key is: "2111" is the Sylvester, GA plant identifier; "5" is the year 2005; "055" the Julian date, in this case 2/24/05; "00" is a space filler; 1037 is a variable military time for filling; and "A" is the A line (firm also has (b)(4) lines for consumer products). The "Best By" date is 18 months from the production date. Note that at one time the firm's plant identifier character began with the letter "S". Mr. Matis speculated that this character was misread as a "5" in some of the complaints FDA had received.

Codes are inked on jar lids and on the plastic over wraps of cases. Exhibit 2 shows a case label with the code occupying the 2 lines left of the bar code. Case codes are basically the same, but with the time following the line indicator. Note display units assembled for (b)(4) stores lack case over wraps. However, individual jars within each flat are coded and the firm records jar codes on shipping documents for each pallet of display units prepared. Mr. Matis showed this to me and explained that in some instances these displays may contain commingled codes.

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Incidentally, this is the only location that makes Peter Pan brand. The same code is used on (b)(4) (b)(4) products made here (b)(4) brand, and at least (b)(4) other manufacturer also makes peanut butter for (b)(4)

COMPLAINTS / PRODUCT DEFECTS

Since the previous FDA contact here was conducted to follow-up complaint 22892 received on 1/12/04, only complaints received by FDA since were covered during the current inspection. Copies of the FACTS complaint entries for each are attached and can be reviewed for additional details.

These complaints include:

24675 dated 4/16/04, reporting a blonde or gray hair found in an 18 oz. jar of Peter Pan Peanut Butter;

25509 dated 6/7/04, reporting an open or loose jar seal and what the consumer described as injection sites in a 40 oz. jar of (b)(4) Peanut Butter;

27728 dated 10/15/04, reporting a small, triangular piece of plastic in an 18 oz. jar of Crunchy Peter Pan Peanut Butter;

27977 dated 10/28/04, reporting what consumer described as mouse droppings, in an 18 oz. jar of Peter Pan Honey Roasted Crunchy Peanut Butter;

28611 dated 12/8/04, reporting two pieces of uncooked rice in a 40 oz. jar of Peter Pan Creamy Peanut Butter;

29134 dated 1/13/05, an anonymous complaint reporting several issues at the firm that in summary allege poor sanitation practices, poor quality program management and poor facilities maintenance.

On 2/23 I briefly summarized each of the complaints above by providing to Messrs. Gentle, Matis and Young the following information for each: date (FACTS date) of the complaint, the geographical (city & state) location, the problem reported, and any specific product identification reported by the consumers.

Regarding complaint 29134, I reported to them the allegations of microbial problems in peanut butter and firm's inadequate response to such, inadequate cleaning of new equipment, and insect activity in the plant. I summarized the complaint in the same manner it is summarized on the attached FACTS complaint report, reporting to them the complaint contained additional allegations that indicated poor sanitation practices, poor quality program management, and poor facilities maintenance.

Mr. Gentle said the firm's policy is to openly communicate complaint information it receives to employees. He said this is done at meetings with employees and with informational postings, and is done so that employees can look out for the potential sources of complaints.

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He said there was a micro hold of some product in October of 2004 and the product was destroyed, and the employees here knew this. He said the firm has and continues to install new equipment here and this activity has resulted in the reduction in the number of employees, and he reported that there has been some dissent here related to a number of people losing jobs. Mr. Gentle reported the firm is going to automated jar handling equipment including finished product palletizing and that equipment is cleaned before it is put into use, but added that is not in an area where the product is contacted.

Mr. Matis reported the firm does perform micro testing and finished product is not released until tested and found within specifications. He added that the micro information in this complaint appeared to be in the same time frame as the dismissal of a (b)(4) in November of 2004. He reported corporate human resources personnel came to the firm to handle the dismissal. He did not elaborate other than to say the dismissal resulted from behavioral issues with other employees.

I inquired as to the reason for the micro hold and how much product was destroyed but Messrs. Gentle and Matis said they could not provide that information until checking with corporate officials. On 2/24 they subsequently reported that the product in the October incident did not meet specifications and was destroyed, but they could not provide any further specific details.

On 2/23 during the course of the inspection I was shown new (b)(4) that had been installed on the peanut butter line in October of 2004. (b)(4) are heat exchangers that, in this application, are used to cool the butter temperature from approximate (b)(4) degrees F prior to it being pumped to the fillers where it is filled at a temperature of about (b)(4) degrees F. The interior piping of the (b)(4) is a food contact surface, with the pipe passing through a cooling medium to effect the temperature change. I inquired then as to how this new equipment had been cleaned. Mr. Young reported the (b)(4) were dismantled, cleaned and sanitized, and that documentation would record that. I asked if the equipment was swabbed or checked in some manner to validate the effectiveness of the cleaning. Mr. Matis said it was most likely swabbed. I asked to see the records of this cleaning and results of any testing verifying its adequacy as an example of the firm's procedures for new equipment installation.

On 2/24, Mr. Matis reported that the (b)(4) in question were cleaned and sanitized in place with (b)(4). He said that the (b)(4) were sealed up following the sanitizing before QA got to them, so no swabs were collected. However, after consultation with his corporate office, he said he had been authorized to show me the finished product testing results from the installation date and the date the (b)(4) went on-line. One date shown to me was for the production date of 10/6-7/04, the date the units were installed, and the other for 10/12-13/04, the date the units were placed on line. He said the finished product tests on both dates were negative for Salmonella and <10 cfu/gram for coliforms. I examined these 2 pages and observed the tests for Salmonella on both dates were recorded at 0.03, and at <10 for coliforms.

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Addressing the hair complaint (24675), Mr. Matis reported the firm has changed to requiring employees to wear the solid type hair nets as opposed to the ones with open-weaves.

Regarding complaint 25509, I advised this was handled as a retail tampering complaint, but I was providing the firm this for informational purposes. Mr. Gentle asked again what was reported and I explained that the consumer reported what looked like injection sites in the butter beneath the unsealed foil.

Mr. Gentle asked if the complainant (27728) had provided the color of the triangular piece of plastic. I told him no. He said this could possibly be a piece of plastic from the rim of the jar.

Mr. Gentle said that dark or burnt pieces of peanut would account for something that looked like mouse droppings (27977).

Mr. Matis said the creamy product (28611) is completely homogenized, so there should be no rice in it. I asked if the firm used any palletized glue, etc. in production and was told no, there was nothing that would appear as rice.

I asked to review the firm's complaint file. Mr. Matis reported the firm had no complaint file per se, and he explained how the firm receives and handles complaints. He reported the firm normally does not receive consumer complaints directly here, but at the corporate level (note a toll free number for questions or comments is printed on product labels). He said the firm receives an electronic notification from corporate headquarters advising of any complaint and the nature of the complaint. Locally, the complaint is investigated and appropriate action taken if necessary. He indicated the firm was aware already of some of the complaints I had reported.

Later, during the plant inspection, he pointed out a complaint posting on an employee bulletin board in a production area. The posting was a to-date summary (for firm's 2005 fiscal year, which runs from May to May) of the numbers and types (by several categories) of complaints. I did not record this information for every category, but thus far and since May of 2004, the firm has received approximately 40 plastic, 30 insect, 20 hair, and 30 foreign object complaints.

OPERATIONS, PERSONNEL, AND EQUIPMENT

The firm is currently operating from 4 to 6 days per week, running 2/10 hour shifts per day. The first shift runs from 6 AM to 4 PM, and the second shift from 4 PM to 2 AM. Sanitation operations are staffed 24 hours per day, with any major clean-ups performed during the down time from 2 to 6 AM. Other sanitation functions are conducted as needed and where needed throughout the production shifts.

Sanitation/Microbial Testing/Pest Control

Equipment is cleaned in place or broken down for cleaning, and sanitized with (b)(4) Any wet cleaning is performed in one specific area and any equipment wet cleaned is dismantled and

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removed to that area for the cleaning. Any new product contact equipment installed is reportedly cleaned and sanitized with (b)(4) at installation, and normally microbial swabs taken. Mr. Matis reported the firm has a routine swabbing program that includes different areas and/or equipment each week. The swabs determine coliform levels and total plate counts.

On 2/24/05 and after having consulted with his corporate office, Mr. Matis provided a verbal overview of the firm's finished product microbial testing program. All finished product is tested in house for Salmonella and coliform. Samples of sealed jars are collected across the shift's production and tests are performed on composites from those samples. All product is held pending results which are returned typically in about 25 hours for 1st shift production, and 48 hours for 2nd shift production.

Product must test negative for Salmonella and must coliform test at no more than (b)(4) u (colony forming units) per gram. If tested at (b)(4) fu/gram or lower, the product is released for distribution. Only the QA Manager or the firm's microbiologist can release a lot based upon this testing, and one or the other is always present for this purpose.

The firm attempts to identify a cause for any findings above (b)(4) FU/gram in finish product, and this is addressed by an action plan which requires the plant to contact its corporate headquarters for guidance. Product testing at between (b)(4) fu may be sold as other than top grade product, but that decision rests with the corporate office, as is the disposition of any testing at over (b)(4) fu. Mr. Matis did not elaborate as to what dispositions are made.

Pest control is handled by an outside national contractor, (b)(4) whose local agent is (b)(4) (b)(4) Mr. Young reported that (b)(4) comes to the firm every (b)(4) and provides a total control package for insects and rodents. I observed rodent catch traps placed near exterior openings and Mr. Gentle reported insect pheromone traps were placed throughout the facility.

In light of the complaint alleging insect infestation, I inspected equipment in the pre-cleaning, sorting blanching and roasting areas, including bins, conveyors, elevator boots and buckets. I also examined several bulk (and previously used) cardboard boxes in which floor sweepings are accumulated for disposal. I examined the aspiration system at collection points over destoners, blanchers, etc., and traced the overhead lines to the maintenance shop where the material is collected, and from there augured on to the exterior trailer loading area where peanut skins and meal are dumped into a trailer and shipped locally for animal feed use. I examined some of this material in one of the trailers being loaded as well.

Accumulated spilled ingredient material along the wall/floor junctures on the sides and behind the air handling cabinet in the ingredient room (equipment here meters (b)(4) into the process) was examined. I found no insect activity in or around any of this equipment or locations, nor did I note any webbing, frass, or other evidence except for 1 moth as described below.

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The moth was flying about an area immediately outside the door from the precleaning room to the enclosed garage where bulk trucks of peanuts are unloaded. 2 tanker truck trailers were parked in here at the time and an employee was connecting one to the firm's piping line that pneumatically unloads the peanuts into storage bins within the plant. As we exited the door from the precleaning room, an employee in the garage was closing one of the 2 fabric-type doors that trailers enter through (the other was already close). Note that when the precleaning room door is opened, an air curtain device mounted overhead automatically directs a strong air flow away from the door opening into the garage.

General Processing Flow/Equipment

The equipment and process found here appears typical to the industry. No unique or unusual equipment was observed. Only a brief description of the process follows.

Raw peanuts are received in bulk trucks and pneumatically off-loaded into bulk bins for temporary holding. Mr. Matis said the firm normally received only bulk trucks of peanuts, but in years when aflatoxins are a concern in the local crop and the firm gets in shipments from blanching facilities, it does receive peanuts in bulk cardboard totes. A system is here for unloading these totes, but it was not in use.

From the bulk holding bins the raw nuts are conveyed to a de-stoning operation that mechanically removes foreign materials through vibratory screening and aspiration. Equipment here is typical of peanut shellers (b)(4). Cleaned peanuts are then conveyed to a holding bin that gravity feeds the stainless belt of the firm's roasting oven. Roasting times vary depending on the desired results for product applications. The oven has (b)(4) roasting zones and (b)(4) holding zones and the belt moves the peanut bed (about (b)(4)ches in depth) through each zone in (b)(4) minutes. Mr. Matis reported in general, peanuts are roasted up to about (b)(4)degrees F. The times and temperatures within the roaster are monitored in a control room where the information is electronically charted.

After roasting, nuts are conveyed in a vertical bucket elevator to holding bins that feed the blanchers. The firm's (b)(4) blanchers remove the skins from the roasted nuts (skins are aspirated from the flow after blanching), and the nuts are then conveyed through an electronic sorting system (b)(4) (b)(4) which rejects dark nuts, foreign matter, etc. from the product. Rejects go through additional blanching and electronic re-sorts before final rejects are discarded and peanuts passing through the sorts go to the primary grinders or mills. From the point peanuts enter the primary mills the butter is made in a closed system.

Up to this point it should be noted that the firm does have some open-topped bins in which raw and roasted peanuts are held, and in places, the product flow is not totally covered, including an area near the exit end of the roaster. I examined these areas when I encountered them and this includes

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examining the tops of some bulk holding bins. I did not find any insect evidence, leaking water pipes, condensation, flaking paint, or other potential overhead contaminants in the areas I examined.

(b)(4) and other ingredients are added at the (b)(4) mills, and the resulting butter is pumped in stainless piping through a series of stainless holding tanks, de-aeration tanks, homogenizers, and then the (b)(4) before going to filling machines. At the filling machines the process is again open between the filling equipment and the closing equipment.

Only creamy peanut butter was observed in production. To make crunchy peanut butter, roasted peanuts are diverted in the product flow prior to the (b)(4) mill and go through a chopping process, and then mixed with butter at the filling locations.

The firm has (b)(4)ling or packaging lines (b)(4)unting a drum filler), designate (b)(4)

During this inspection the firm was filling creamy peanut butter into 18 oz., 28 oz., and 6 lb. containers. Empty jars or containers are inverted and blown out prior to filling and jars pass through a detector to insure they are right side up before filling. Empty jar/container lines are covered from the inversion points to the fillers. The firm is in the process of installing completely automated container handling systems which eliminate any manual removal of containers from cases.

Peanut butter is mechanically filled at about (b)(4) degrees F on rotating fillers and the filled jars or containers exit the fillers and pass on a conveyor through fill weight and metal detectors before being capped or closed. With a couple of exceptions noted in the next heading and reported to the firm, the conveyors transporting the filled but uncapped containers are covered. After capping, jars pass through a dud detector that checks for proper cap seating. Jars pass through a (b)(4) heat sealing machine which applies heat to the tops necessary to attach the foil-seal to the jar rim beneath the cap.

After heat sealing, jars are labeled (composite cans are received labeled from the supplier) jar/container lids are coded, then mechanically assembled into tray packs (cases) which are shrink wrapped in clear plastic, which is case coded.

The firm does assemble display units for (b)(4) stores in which the individual cases are not over wrapped in order that customers may easily remove jars from the display. Consequently, these cases lack the case code, but individual jars are coded and the code information is recorded on shipping documents prepared during the display assembly. These assemblies are basically standard pallets upon which unwrapped cases of peanut butter are stacked, and contain cases of both crunchy and creamy peanut butter. These may contain commingled codes if assembly runs from one day to the next.

Finished products are initially stored on-site in the firm's warehouse. The warehouse is also used for storage of packaging materials (jars, cases, etc.).

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Management reported that in general, regular creamy and crunchy peanut butter is shipped out within (b)(4) of production, and some of the slower moving items would go out in about (b)(4) of production. Mr. Matis said that product is shipped to ConAgra distribution sites. If the site is within (b)(4) or less from Sylvester, the product is shipped by regular truck, if further, by refrigerated truck.

Mr. Matis reported the firm has not recalled any product, other than in successful episodes of mock recalls.

INSPECTIONAL OBSERVATIONS

No FDA-483 was issued at the inspection's conclusion. However, several observations were noted and discussed with the firm's management on 2/23 and on 2/24.

On 2/23/05 it was noted that there were areas on 2 packaging lines where filled, but un-closed, containers of peanut butter were not completely covered. One area was an approximate 3 foot section on the conveyor transporting filled 18 oz. plastic jars to the capper on line A, near the jar entrance to the capper. Here the jars veered at a slight angle toward the capper, away from the cover in place overhead. This resulted in the jars having no overhead protection, even though a cover was present.

The 2nd such area was on the (b)(4) line, used for packaging the 6 lb. composite cans. On this line, there was an approximate 6 foot length of the conveyor exiting the filling machine that was not covered at all. Filled 6 lb. containers of peanut butter passed through this section of conveyor with no overhead protection.

As noted previously, a live moth was observed in the truck unloading garage.

There was an accumulation of spilled ingredient materials at the wall/floor junctures to the sides and behind a large air handling cabinet in the ingredient dispensing room.

A piece of cardboard was observed being used as a baffle on an empty jar line, as the jars changed direction on conveyors from an inverter to a filling machine. The jars came into contact with this cardboard.

REFUSALS

Mr. Matis cited corporate policy in refusing to provide review of written microbial testing procedures and written equipment cleaning/validation procedures. He did however, provide verbal overviews and he allowed access and review of results of finished product microbial testing on peanut butter made on dates in October of 2004 when new (b)(4) were installed.

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Mr. Matis declined to answer a question regarding whether or not posted aflatoxin test results on raw peanut bins were from USDA certificates received with the lots or the result of in-house aflatoxin testing.

GENERAL DISCUSSION WITH MANAGEMENT

During the inspection and then at the conclusion of the inspection I verbally identified the issues reported above under inspectional observations. Mr. Matis reported the firm welcomed the inspection as it afforded an outside perspective on the operations here. He reported on 2/24 that both the areas on the filling lines had been corrected between 2/23-24/05 (I confirmed this on the A line during sample collection). He reported the cardboard baffle had been removed and the jars moved along like they were supposed to anyway so he had no idea why it was there in the first place.

Mr. Matis said the area in the ingredients room was a difficult area to clean, and the material accumulated quickly there.

I did not issue any warnings. I advised of my intentions to collect a sample of peanut butter for microbial analysis.

VOLUNTARY CORRECTIONS

See the above discussion.

SAMPLES COLLECTED

On 2/24/05 I collected sample number 308388, Peter Pan Creamy Peanut Butter in 18 oz. plastic jars, from the firm's packaging line. A copy of the collection report is attached. The sample consists of 15 jars collected in duplicate at the rate of 2 from each of 15 full cases removed from the production line at approximate 5 minute intervals beginning at 10:05 AM. Approximately (b)(4) cases passed per 5 minute interval. The sample was submitted to SRL for microbial analysis (Salmonella, Listeria, and coliforms).

Mr. Matis advised the firm would voluntarily hold the production from this date pending a report of the FDA analytical results.

EXHIBITS

- 1- Plant Confidentiality Agreement
- 2- Case Labeling
- 3- Miscellaneous Shipping Ticket (for sample 308388)
- 4- 18 oz. Peter Pan Creamy Peanut Butter Labeling
- 5- 28 oz. Peter Pan Creamy Peanut Butter Labeling
- 6- 6 lb. Peter Pan Creamy Peanut Butter Labeling

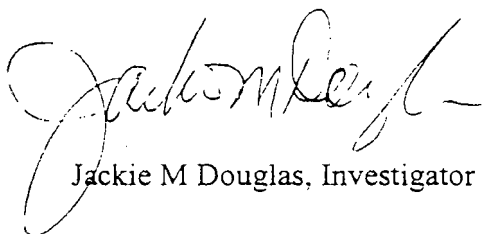
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ATTACHMENTS

FDA-482, Notice of Inspection
FDA-484, Receipt for Samples
Copy of Collection Report 308388
Complaint Report 24675
Complaint Report 25509
Complaint Report 27728
Complaint Report 27977
Complaint Report 28611
Complaint Report 29134



Jackie M Douglas, Investigator