

Establishment Inspection Report

Setton’s International Foods, Inc.
Commack, NY 11725-5701

FEI: **2433583**
EI Start: 03/31/2009
EI End: 04/08/2009

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SUMMARY (JC)

This comprehensive inspection of manufacturer, repacker and wholesale distributor of nuts, snacks and candy was conducted pursuant to FACTS assignment # (b) (4) and as a follow-up to the recall initiated at Setton Pistachio of Terra Bella, Inc., as Setton’s International Foods, Inc is a direct customer of the recalling firm. This inspection was conducted during normal business hours in accordance with Compliance Program 7303.803, Domestic Food Safety under PAC 03R856.

The previous inspection (03/09/09) conducted under the 2008-2009 FDA/NY State Contract was classified as OAI. Critical deficiencies were noted as follows: one live cockroach was noted on an ingredient rolling rack in the chocolate tank mixing storage room; and one live cockroach was noted on the wall behind the equipment wash sink in the employee break room. Several general sanitary deficiencies were also noted.

The current inspection covered the follow-up to the recall initiated at Setton Pistachio of Terra Bella, Inc. as Setton’s International Foods, Inc. is a direct customer of the recalling firm. The inspection also covered the new recall conducted at Setton’s International Foods, Inc. as the firm repackaged and manufactured products using the recalled products as raw ingredients. The firm’s manufacturing

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and repacking processes for pistachios were covered during this inspection and the following procedures and records for February and March 2009 were reviewed: Food Allergen Control Plan, Master Cleaning Schedule Procedures, Equipment Cleaning Procedures, Internal Preventative Pest Control Procedures, External Preventative Pest Control Program, Daily Metal Detection Sensitivity Test Sheet, Initial Scale Weight Check Log, Master Cleaning Schedule Log, Weekly Insect Trapping Report, External Preventative Pest Control Program Log and Fogging Log.

The current inspection resulted in a VAI classification. A FDA 483, Inspectional Observations, was issued for the following: failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food and food-contact surfaces; sanitizing agents are inadequate and unsafe under conditions of use; employees did not wash hands thoroughly in an adequate hand-washing facility at any time their hands may have become soiled or contaminated; failure to provide hand washing facilities at each location in the plant where needed; failure to wear hair restraints where appropriate; and failure to provide safety-type lighting fixtures suspended over exposed food.

In addition, the following verbal observations were discussed with management during the closing meeting: chocolate was noted on the floor by the dumpster located to the east of the back entrance; lights were noted unshielded throughout the warehouse; an approximately 1/4 inch gap was noted at the bottom of the pedestrian door by the back loading dock; three holes noted in the walls of the walk-in refrigerator; and three brooms were noted in the panning room between coating pan (b) (4) and polishing pan (b) (4). Management promised corrections.

Samples (b) (4) and (b) (4) consisting of (b) (4) environmental swabs and sponges were collected throughout the processing facility. In addition, finish product samples (b) (4) and (b) (4) were also collected. The samples were sent to the FDA Northeast Regional Laboratory for salmonella analysis.

Management stated that the facility has a strict policy against photography; therefore, photography was refused during this inspection.

A copy of the Guidance for Industry: Food Producers, Processors, and Transporters Food Security Preventive Measures brochure and the ALERT Card were provided to and discussed with management.

(b) (3) (B)

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ADMINISTRATIVE DATA (JC)

Inspected firm: Setton's International Foods, Inc.
Location: 85 Austin Boulevard
Commack, NY 11725-5701
Phone: (631) 543-8090
FAX: (631) 543-8070
Mailing address: 85 Austin Boulevard
Commack, NY 11725-5701

Dates of inspection: 3/31/2009, 4/1/2009, 4/2/2009, 4/6/2009, 4/8/2009

Days in the facility: 5

Participants: Jane Chen, Investigator
Frank Verni, Investigator
Matthew R. Palo, Investigator
Sarah A. Wangseng, Investigator

Inspectional Team: Jane Chen, Investigator (Present throughout the entire inspection)
Frank Verni, Investigator (Present 03/31/09, 04/01/09, 04/06/09 & 04/08/09)
Matthew R. Palo, Investigator (Present 03/31/09, 04/02/09 & 04/08/09)
Sarah A. Wangseng, Investigator (Present 04/02/09 & 04/08/09)
* Sections of this report were prepared by Frank Verni and I (Jane Chen). Initials have been placed in parenthesis to the right of each section heading to designate who prepared which section.

FDA Forms Issued: FDA-482, Notice of Inspection, dated 3/31/09 issued to Mia R. Cohen, Chief Operating Officer as she indentified herself as the most responsible person at the time of the inspection (Attachment #1)
FDA-482, Notice of Inspection, dated 04/02/09 issued to Mia R. Cohen, Chief Operating Officer as she indentified herself as the most responsible person at the time of the inspection (Attachment #2)
FDA-484, Receipt for Sample, dated 04/08/09 issued to Mia R. Cohen, Chief Operating Officer (Attachment #3)
FDA-484, Receipt for Sample, dated 04/08/09 issued to Mia R. Cohen, Chief Operating Officer (Attachment #4)
FDA-483, Inspectional Observations, dated 04/08/09 issued to

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Mia R. Cohen, Chief Operating Officer (Attachment #5)

Credentials Presented to: Mr. Joel Ginsberg, Warehouse Manager
Mr. Allen Jao, Packaging and Production Manager of Packaging Department
Troy Simmons, Production Manager of Roasting Room
Alan Tchaikowitz, Manager of Panning Room
(b) (4), Counselor at Law (b) (4)
(b) (4), Senior Consultant of (b) (4)

Regulatory Agencies: On 04/01/09, Ms. Angela Montalbano, Food Safety Inspector; Mr. Steven Vanness, Supervising Food Inspector; and Ms. Phyllis M. Black, Supervising Food Inspector from the New York State Department of Agriculture & Markets, were at the firm to conduct an inspection. They stated that they heard of the recent recall and was sent to the firm to follow up, collect samples and conduct an inspection. They had conducted their own independent inspection of the facility and collected samples prior to our arrival. Credentials were presented to Ms. Montalbano, Mr. Vanness and Ms. Black. We informed them that we were in the middle of conducting an inspection. They departed prior to the start of our inspection on 04/01/09.

Rabbinical Supervision: Rabbi (b) (4)

HISTORY (JC)

Legal Status: New York State Corporation established in 1971.

Related Firms: No other legally related firms.

However, the firm’s majority owners are also majority owners of Setton Pistachio of Terra Bella Inc. (Terra Bella, CA). The two companies share administrative resources and both have Joshua Setton as Chief Executive Officer (Exhibit # 4). Setton’s International Foods, Inc. maintains that they are only a customer of Setton Pistachio of Terra Bella, Inc.

According to Mia Cohen, the legal name of the firm is Setton’s

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International Foods, Inc. The firm uses Setton International Foods, Inc. as their DBA.

Previous Inspection /
Relevant Recalls:

The previous inspection (03/09/09) conducted under the 2008-2009 FDA/NY State Contract was classified as OAI. NY State sent the firm a warning letter.

According to Ms. Cohen, there have never been any recalls prior to the current recall (see "RECALL & RECALL PROCEDURES" section of the report.

Hours of Operation:

(b) (4)

Employees:

(b) (4) for the facility which includes (b) (4) employees working in processing / the warehouse

Layout of the Facility:

The firm was originally located in Plainview, New York until it moved to the current location 16 years ago. The facility consists of a (b) (4) square foot one story building with (b) (4) feet of processing area. The one story facility consists of offices, warehouse, packaging department, roasting room, a walk-in refrigerator, panning room, organics room, loading docks and employee break room, locker rooms and restrooms (Exhibit #s 6 &7).

Annual Sales:

Annual sales are approximately (b) (4), according to Ms. Cohen.

Registration Status:

As per Ms. Cohen, the firm is registered with the Food & Drug Administration under the provisions of the Bio-Terrorism Act of 2002.

FDA Correspondence:

Joshua Setton, Chief Executive Officer
85 Austin Boulevard
Commack, NY 11725

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INTERSTATE COMMERCE (JC)

The firm manufactures, repacks and wholesales nuts, snacks and candy nationwide and to Canada. The firm also distributes products prepared by contract manufacturers under the Setton Farms brand. In addition, the firm imports its raw ingredients from countries including: (b) (4)

The firm purchases raw ingredients from numerous suppliers, including:

Setton Pistachio of Terra Bella, Inc.
Terra Bella, CA
Pistachios

(b) (4)
Dried Cranberries

(b) (4)
Almonds

(b) (4)
Prunes

These products are classified as food under the Food, Drug and Cosmetics Act and are regulated by the Food and Drug Administration.

The firm sells (b) (4) wholesale with (b) (4) interstate sales. A majority of the firm’s customers are retail stores and wholesale distributors. The firm has (b) (4) company owned trucks that it uses to make deliveries. The firm also uses third party trucking companies.

The firm advertises its products via word of mouth and through its sales force. Though the firm advertises on its website (<http://www.settonfarms.com/>), the company does not sell products over the internet.

JURISDICTION (JC)

Please refer to Exhibit #s 1-3 for the firm’s product catalogs.

The firm also provided the final product labeling for products under the initial recall by the firm (Exhibit #8).

The firm contracts unrelated manufacturers to manufacture and pack other products under the Setton Farms label. In addition, the firm is a private labeler for the following: Corrado’s and Fairway.

The Setton Farms brand name is used by both Setton’s International Foods, Inc. and Setton Pistachio of Terra Bella, Inc. and both companies are listed on the final product labels. However, Setton Pistachio of Terra Bella, Inc. has ultimate responsibility over the brand name. As the two companies

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packaged products in different types of containers, they are able to differentiate which company is ultimately responsible for a product under the same Setton Farms brand.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED (JC)

On March 31, 2009, Frank Verni, Matthew R. Palo and I (Jane Chen) presented our credentials and issued an FDA 482, Notice of Inspection, to Ms. Mia R. Cohen, Chief Operating Officer (Attachment #1). Ms. Cohen identified herself as the most responsible person present at the time of the inspection.

On April 02, 2009, we issued another FDA 482, Notice of Inspection, to Ms. Mia R. Cohen, Chief Operating Officer as Investigator Sarah Wangseng joined the inspection team (Attachment #2).

On April 08, 2009, two FDA 484s, Receipt for Sample, and an FDA 483, Inspectional Observations were issued to Ms. Mia R. Cohen, Chief Operating Officer (Attachment #s 3-5).

During the inspection, Ms. Cohen and Mr. Ginsberg answered our questions and provided us with information regarding the firm. Mr. Ginsberg and ^{(b) (4)} [REDACTED] accompanied us on the walkthrough of the firm. Mr. Troy Simmons, Mr. Alan Jao and Mr. Alan Tchaikowitz, Managers, answered our questions regarding their respective areas during the walkthrough. Mr. Simmons, Mr. Jao and Mr. Tchaikowitz all report to Mr. Ginsberg.

Ms. Cohen and Mr. Ginsberg both refused photography and cited the firm's policy as the reason for refusal.

Ms. Mia Cohen is the Chief Operating Officer of the firm and she indicated her responsibilities include handling special projects for the firm. Mr. Joel Ginsberg, General Manager, is in charge of all operations of the warehouse and the processing areas. Both Ms. Cohen and Mr. Ginsberg report to Mr. Joshua Setton, President and Chief Executive Officer. During the inspection, Mr. Joshua Setton was not available at the firm as he was away on a business trip.

Corporate Structure: Joshua Setton, Chief Executive officer
Mia R. Cohen, Chief Operating Officer
Steward Vellner, Chief Financial Officer
Morris Setton, Executive Vice President

Refer to Exhibit # 5 for the firm's organizational chart.

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FIRM'S TRAINING PROGRAM (JC)

The firm has a formal employee training program for the employees during orientation and refreshers throughout the year as needed. The firm also hires a outside contractor to conduct OSHA training for the employees at the firm.

MANUFACTURING/DESIGN OPERATIONS (JC &FV)

The firm is a Kosher plant that manufactures, repacks and wholesales nuts, snacks and candy nationwide and to Canada. The firm's production schedule depends on inventory and orders. The firm has a Food Allergen Control Plan to mitigate the risk of cross contamination from allergens (Exhibit #9). As per Mr. Ginsberg, the firm does not conduct internal testing of any kind.

All products repacked and manufactured by the firm are weighed and passes through a metal detector prior to shipment. Metal detectors are calibrated at the beginning of each day and after lunch with stainless steel, non-ferrous and ferrous wands. The results are recorded on the Daily Metal Detection Sensitivity Test sheet (Exhibit # 10). All scales are calibrated at the beginning of each day with a block weight and results are record on the Initial Scale Weight Check Log (Exhibit # 11).

The firm has a (b) (4) square foot walk-in refrigerator where it stores raw ingredients to ensure quality. According to Mr. Ginsberg, inventory turnover for the warehouse is approximately (b) (4).

The four processing areas are as follows:

1. ROASTING ROOM

The roasting room is where cashews, almonds, peanuts and filberts are roasted. The firm does not roast any other products. There are (b) (4) roasters in the roasting room as follows:

CASHEW ROASTING LINE: (ROASTER (b) (4))

This line is only used for the manufacturing of roasted cashews (salted and unsalted). The process is as follows:

1. Raw cashews are unboxed and placed into a (b) (4) pound stainless steel hopper.
2. The large stainless hopper is lifted, via forklift, to the beginning of the cashew roasting line where it is emptied into the large primary stainless steel hopper located at the beginning of the line.
3. This large stainless hopper feeds, via gravity, into a conveyor system to raise the raw cashews to the shaker table.
4. The raw cashews are fed to the shaker table, which uses a vibrating action on a perforated table, to remove small cashew fragments and particles. These fragments are disposed in the trash.

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5. After the shaker table, the raw cashews enter a smaller stainless steel hopper that feed into the roaster. This hopper is equipped with an electric eye to alleviate overfill of the machinery.
6. The raw cashews then enter the roaster; here the cashews cook in oil at (b) (4) °F to (b) (4) °F for approximately (b) (4).
7. Once roasting is complete, the cashews move into the cooling tunnel.
8. Workers use a large stainless steel tool to pull the roasted cashews left in the roaster into the cooling tunnel.
9. After the roasting process, the cooked cashews enter a cooling tunnel, which is run via a conveyor belt, to bring the temperature of the product down.
10. The roasted cashews then pass through a Salter which applies salt to the cashews (the Salter is turned off during the production of unsalted cashews).
11. The roasted cashews then feed onto an exit chute were workers manually place the roasted cashews into plastic bag lined cardboard boxes.
12. The boxes are on top of scales to achieve the desired weight.
13. Once the desired weight is achieved, the box is taped closed.
14. The sealed box is then passed through a metal detector and placed on pallets.

NUT ROASTING LINE (ROASTER (b) (4))

This line is used for the manufacturing of all roasted nuts (salted and unsalted) except for cashews. The firm roasts mostly almonds, filberts, and peanuts.

We did not observe this line operating during our inspection. The line runs in the same fashion as the cashew roasting line except for the following:

1. Nuts are placed in a large stainless hopper which is suspended over a shaker table by a forklift at the beginning of the line. The forklift holds the hopper over the line for the duration of manufacturing.

CLEANING AND SANITATION

According to Mr. Troy Simmons, Production Manager in the Roasting Room, air from an air hose is used to remove any residues from the conveyor belts and roasters at the end of (b) (4) and between (b) (4) s of different nuts from Roaster (b) (4).

Mr. Simmons stated that the oil in the roasters is changed (b) (4). The oil from both machines is filtered using the same paper filtering system. Filtration is more effective on cooled oil so the filtering system is in operation for a (b) (4) in the morning, (b) (4) during lunch and an half an hour after production. If the roaster is not being used, the oil is filtered (b) (4).

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A full breakdown of the roasters occurs each month. Once broken down, the roaster is power washed with water and (b) (4) Degreaser. No bleach is used on the roasters; however, the firm's Equipment Cleaning Procedures call for the use of bleach (See Observation # 1). According to Ms. Simmons, bleach is only used on the floors of the Roasting Room. Breakdown of the roasters for cleaning was not observed during this inspection.

2. PANNING ROOM:

The firm makes several chocolate coated nut and dried fruit products. All these products are made in the panning room. The panning room consists of (b) (4) coating pans and (b) (4) polishing pans where chocolate coating is conducted as follows:

CHOCOLATE COVERED PRODUCTS:

1. Chocolate is melted in one of (b) (4) (b) (4) tempering machines (b) (4) with a (b) (4) lb. capacity and the (b) (4) having a (b) (4) lb. capacity) which are located in a room right outside the panning room.
2. Once the chocolate reaches the proper temperature and consistency, it is pumped, via stainless steel tubing, through the wall into (b) (4) of (b) (4) (b) (4) panning machines; at this point, the panning machine is filled with the product to be chocolate coated.
3. The chocolate enters the panning machine via a spray nozzle which is controlled by an operator. As the chocolate is being sprayed, the panning machine rotates to evenly coat the product.
4. Once the product is properly coated, it is left to sit for a period of time. The length of time depends on the product and environmental conditions.
5. The chocolate coated product is then polished using (b) (4) of (b) (4) (b) (4) polishing machines. The machine rotates as a polishing agent is applied; giving the finished product an even and glossy exterior appearance.
6. The product is then packaged as per customer order or in bulk packaging.

* During the current inspection, the panning room was not in operation due to construction.

CLEANING AND SANITATION

Alan Tchaikowitz, Manager of Panning Room, states the pans are washed with hot water and detergent. The water will be removed in plastic buckets and replaced with hot water boiled in the range to rinse the pans. The buckets are stored in a locked cabinet by the chocolate tempering machines.

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3. ORGANIC ROOM

The firm repacks organic products in a dedicated room. All packaging, labeling, raw materials, and finished products that are for organic use are stored and repacked in this room. The firm is certified organic.

The firm only produces approximately (b) (4) of organic products annually.

Please refer to the Cleaning and Sanitization of the Packaging Department as the process is the same as the cleaning and sanitization conducted in the Organic Room

4. PACKAGING DEPARTMENT

The firm manufactures (b) (4) blended mixes and repacks a variety of items in their facility. The general process is as follows:

1. If the product has to be mixed, separate ingredients are weighed and added to (b) (4) blenders (one blender is dedicated to Passover products).
2. Mixing is done according to a production sheet which is checked off by the production manager. Verbal approval must be obtained from manager prior to mixing and all lot code of raw ingredients must be entered into the system.
3. The ingredients are allowed to mix for a predetermined amount of time depending on the product being manufactured.
4. Once fully mixed, the product is emptied into stainless steel hoppers and placed next to the packaging lines.
5. If the product is repacked by the firm, the process begins at this step. The product is transferred into smaller stainless steel bin located on the packaging lines.
6. At this point, workers manually apply labeling to the empty containers.
7. Workers then manually fill the container with the product while simultaneously verifying the weight on scales.
8. A lid and a plastic safety seal are applied.
9. The product then proceeds into a heat tunnel which shrinks the safety seal applied to the lid / container junction in the previous step to a tight fit.
10. The product is boxed, passed through a metal detector and palletized.

NOTE: The above process takes place on the firm's (b) (4) manual packaging lines, named (b) (4). The firm also has a semi-automatic packaging line, named SA, which works the same as the manual lines except that labeling is applied by the machine. The firm also has a fully automatic packaging line, named PL, which is not yet in use. During our inspection, only the manual packaging lines, named (b) (4) and (b) (4) were in operation.

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CLEANING AND SANITATION

Cleaning was witnessed throughout the inspection. Employees rinse the stainless steel food bin at the three compartment sink in the employee break room. The bin is then sprayed with bleach and water solution and dried with paper towels. The rest of the packaging line is just sprayed with bleach and water solution and wiped dry with paper towels.

According to Mr. Jao, no detergent is used. In addition, he states that the employees use (b) (4) bleach and water solution. When asked for a test strip to test the concentration, Mr. Jao states that the firm does not have a test strip. When tested, the bleach and water solution turned the investigator's test strip white. The solution was diluted with approximately (b) (4) times the volume of water and retested. The concentration of the diluted solution tested at greater than (b) (4) ppm chlorine (See Observation #2).

SANITATION

The firm has Master Cleaning Schedule Procedures, Equipment Cleaning Procedures and Master Cleaning Schedule Log which illustrates the procedures for cleaning and records that must be maintained. However, the Master Cleaning Schedule Log does not include all items to be completed as indicated in the firm's cleaning procedures (See Observation #1).

Garbage is picked up a couple of times a month by (b) (4)

PEST CONTROL

The firm has an internal pest control program for the warehouse and processing areas (Exhibit# 16). The pest control procedures call for (b) (4) inspections of (b) (4) and (b) (4). In addition, insect traps are checked (b) (4) in the summer and (b) (4) in the winter. Insecticide (b) (4) is also conducted at the firm (Exhibit # 18); however, this was not observed during the current inspection.

The firm hires an external company for the office and the exterior grounds (Exhibit #17). The firm's extermination company is (b) (4), located in (b) (4). The extermination company visits the firm every two weeks.

During our inspection, no evidence of pests was noted in the facility. Records reviewed for February and March 2009 show no indication of pests in the warehouse or processing areas.

MANUFACTURING CODES (JC)

The firm prints the expiration date on each retail packaging. Shelf life for all products except organics is (b) (4). Organic products have a shelf life of (b) (4). For a product with a shelf life

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of (b) (4) manufactured or repacked on (b) (4), the expiration date on the retail packing would be (b) (4). However, there are instances where the sales person would receive an advance order and request labels to be printed prior to manufacturing / repacking. This will result in an expiration date that would be earlier than one year from manufacturing / repacking on the retail packaging. As per Mr. Jao, in these cases, the labeling will not be printed more than one week prior to manufacturing / repacking. Inquiry was made into this practice as to how it could potentially affect recalls. Mr. Ginsberg stated that he will look into the process.

The firm also prints codes on cases. The firm’s coding system consists of (b) (4) and (b) (4). The letters represent the line as follows:



The (b) (4) indicate the (b) (4) from (b) (4) representing (b) (4). For example, (b) (4) will be depicted as (b) (4). According to the firm’s system, the day changes at noon; therefore, (b) (4) will represent (b) (4) and (b) (4) would represent (b) (4) at (b) (4).

The manufacturing codes on the cases are automatically generated by the computer. The (b) (4) (b) (4) printed are set to the IP address of the printer in the different lines. The (b) (4) depend on when the computer receives the information. For example, the computer can receive the information at (b) (4), packaging can take place after lunch but the case code will indicate (b) (4).

In addition to the manufacturing code on the bulk packaging, the firm also prints product codes on the bulk packaging.

COMPLAINTS (FV)

The firm does not have formal complaint procedures in place. Management stated that no food-borne illness complaints have been received by the firm, only quality complaints.

Due to the fact that Setton Pistachio of Terra Bella, Inc. located in Terra Bella, CA and Setton International Foods, Inc. located in Commack, NY both share the brand name of “Setton Farms”, which also states both firms on the labeling, we asked how customers would know which firm to contact for questions or complaints. Management stated that they routinely receive complaints dealing with products manufactured at Setton Pistachio of Terra Bella, Inc. located in Terra Bella, CA and vice versa. Management stated that the two firms use different lot coding systems and different packaging, so it is easy to differentiate who manufactured the product. Management stated that if a complaint is received on a product manufactured by Setton Pistachio of Terra Bella, Inc. located in Terra Bella, CA, they simply forward the complaint to them and vice versa.

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Management stated that the labeling of products will be reviewed to try to alleviate this confusion in the future.

RECALL & RECALL PROCEDURES (FV)

The firm currently has a recall procedure in place entitled "PRODUCT RECALL PROCEDURE", revised Dec 2007 (Exhibit # 20).

During the first day of our inspection at the firm, on 03/31/09, the firm was actively initialing both a sub-recall and their own new recall of pistachios in response to a nationwide recall by Setton Pistachio of Terra Bella, Inc. located in Terra Bella, CA. The firm was initially notified by Setton Pistachio of Terra Bella, Inc. on 03/24/09 of the recall.

As per Ms. Cohen, the firm has stop all manufacturing and repacking of all pistachios and pistachio containing product in the plant as of 03/24/09. In addition, the firm has stopped all sales of pistachios and quarantined the pistachios in the plant. During the walkthrough, we observed signs posted on pistachios to hold the product. Pistachios were located throughout the warehouse, and we expressed our concern that the pistachios might be shipped out accidentally.

On 04/01/09, the firm moved all quarantined products containing pistachios to a centralized location. The firm also provided us with a list of recalled products that they placed under quarantine and a full distribution list of their direct consignees. On 04/01/09, we were also provided with the following bills of lading indicating shipment of recalled pistachios from Setton Pistachio of Terra Bella, Inc. located in Terra Bella, CA to Setton International Foods, Inc. located in Commack, NY (Exhibit # 21):

DATE	LOT #	DESCRIPTION	NET WT.
10/28/2008	10/28/2008 12:00:00 AM	PISTACHIOS WHOLE KERNELS R/S 25#	2000
		PISTACHIOS WHOLE KERNELS R/U 25#	2000
11/5/2008	2738 W/M	PISTACHIOS WHOLE KERNELS R/S 25#	4000
11/7/2008	11/7/2008 12:00:00 AM	PISTACHIOS WHOLE KERNELS R/U 25#	1575
12/8/2008	12/10/2008 12:00:00 AM	PISTACHIOS WHOLE KERNELS R/U 25#	4000
12/30/2008	12/30/2008 12:00:00 AM	PISTACHIOS WHOLE KERNELS R/S 25#	2000
1/23/2009	1-23-2009	PISTACHIOS WHOLE KERNELS R/S 25#	2000

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3/3/2009	0208 W/M	PISTACHIOS WHOLE KERNELS R/S 25#	2000
		PISTACHIOS WHOLE KERNELS R/U 25#	2000
3/5/2009	0208 W/M	PISTACHIOS WHOLE KERNELS R/S 25#	4000
		PISTACHIOS WHOLE KERNELS R/U 25#	2000

When compared to the original recall assignment sent out by SAN-DO, on 04/01/09, we realized that a shipment was missing as follows:

(b) (4)

Management stated that this particular shipment was ordered; subsequently the order was cancelled, and therefore never sent to Commack, NY.

On 04/02/09, management stated that they had placed all pistachios and pistachio containing products in quarantine status, whether under recall or not, as a precautionary measure. Management provided us with a list of all quarantined products not under recall on 04/02/09 (Exhibit # 22). We were also provided with a list of all pistachio shipments from Setton Pistachio of Terra Bella, Inc. to Setton International Foods, Inc. from 09/01/09 to date (Exhibit # 23).

On 04/03/09, Setton International Foods, Inc. issued a nationwide press release (Exhibit # 24) voluntarily recalling several lots of pistachio products in response to a nationwide recall of pistachios by Setton Pistachio of Terra Bella, Inc. located in Terra Bella, CA. Recall notices were sent to direct consignees starting that evening.

On 04/06/09 Setton Pistachio of Terra Bella, Inc. located in Terra Bella, CA expanded their recall (Exhibit # 25) to include all raw shelled pistachios, roasted shelled pistachios, and roasted in-shell pistachios from its 2008 crop. In light of this new information, Setton International Foods, Inc. started compiling the information it needed to expand their recall.

On 04/08/09, we learned that the (b) (4) had contacted FDA on 04/07/09 because when they learned of the Setton Pistachio recall, they did a search of their import system and came across an importer called (b) (4) who received the product. (b) (4) follow up investigation revealed that (b) (4) had received a sample shipment of (b) (4) and (b) (4) from Setton on (b) (4). With these pistachios, they made a trial product (b) (4) for Setton Farms and all of the samples were sent back to Setton Farms, US for their analysis.

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There were no official labels for this trial product, but the samples ((b) (4)) were given a temporary name as (b) (4). When questioned about this product, on 04/08/09, management stated that the bars were made for them by (b) (4), as a sample to see if it was a product they wanted to further develop. The product was never sold or distributed in the retail market, and they never commercially produced the product.

Our inspection concluded on 04/08/09, at that time the firm had not yet compiled all the information needed to expand their recall.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE (JC)

On April 8th, 2009 during the closing meeting, an FDA 483, Inspectional Observations, was issued to Ms. Mia R. Cohen, Chief Operating Officer. We stated that these were our observations and that they would be reviewed by the FDA to determine violations.

Observations listed on form FDA 483

OBSERVATION 1

Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food and food-contact surfaces.

Specifically,

The firm's SOP entitled "Equipment Cleaning Procedures" is inadequate in that it only calls for a sanitization step without a prior wash step. On 04/02 & 06/09, employees in the Packaging Department were witnessed performing only a sanitization step consisting of wiping both food and non-food contact surfaces with a chlorine sanitizer solution and paper towels.

The firm's SOP "Equipment Cleaning Procedures" (Date Revised: Jan. 3, 2008) relating to the Roasting Department calls for the use of bleach solution. The Manager of the Roasting Room who conducts cleaning of the (b) (4) roasters stated that he only uses a water power wash and degreaser to wash the equipment once every (b) (4). He also indicated that bleach solution is only used on the floors of the roasting room. Other than using an air hose to remove nut residues between batches of different types of nuts, no additional cleaning or sanitizing is conducted on the roasters.

The firm's SOP entitled "Equipment Cleaning Procedures" details the actions employees are to take to ensure equipment is adequately cleaned. It also calls for the completion of the "Master Cleaning Schedule Log" to document cleaning was accomplished according to this procedure however the "Master Cleaning Schedule Log" does not include all of the items discussed in the SOP.

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Reference: 21 CFR 110.35(a)

Supporting Evidence and Relevance:
Exhibit #s 12-15

Equipment should be both cleaned and sanitized to ensure that biofilm, food residue, pathogen and other contaminants are removed to prevent the contamination of food and food contact surfaces.

Discussion with Management:

According to (b) (4), the (b) (4) should not be used as a sanitizer. In addition, the company stated that the manufacturer's instruction for use does not indicate the use of this product as a sanitizer.

We explained to Ms. Cohen that the firm currently cleans in the Roasting Room and does not sanitize. In addition, though sanitization is conducted in the Packaging Department, cleaning was not witnessed. We stressed the importance of both cleaning and sanitizing to management. Ms. Cohen stated that a new standard operating procedure will be established for cleaning and sanitizing for all processing areas. The new procedures will address the observations noted and implemented within a month.

OBSERVATION 2

Sanitizing agents are inadequate and unsafe under conditions of use.

Specifically,

On 04/02/09, employees were witnessed wiping down both food contact surfaces and non-food contact surfaces of Table (b) (4) and Table (b) (4) in the Packaging Department with a chlorine sanitizer solution and (b) (4) paper towels. The Tables are used to package ready-to-eat food items. When requested, the firm did not have sanitizer test strips to test the concentration of the sanitizing solution. When tested with a chlorine test strip, concentration was greater than (b) (4) ppm.

On 04/06/09, the concentration of chlorine sanitizing solution used to wipe down both food contact surfaces and non-food contact surfaces of the Packaging Department tested at greater than (b) (4) ppm with chlorine test strip.

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Reference: 21 CFR 110.35(d)(5)

Relevance:

Concentration of sanitizing solution should not exceed the recommended levels as there is a potential of leaving a residue on the surface and contaminating food and food contact surfaces.

Discussion with Management:

According to Mr. Jao, the employees use (b) (4) bleach and water solution. On 04/02/09, when asked for a test strip to test the concentration, Mr. Jao states that the firm does not have a test strip. When tested, the bleach and water solution turned the investigator's test strip (b) (4). The solution was diluted with approximately (b) (4) times the volume of water and retested. The concentration of the diluted solution tested at greater than (b) (4) ppm chlorine. We informed Mr. Jao that the concentration was too high and may leave a residue on food contact surfaces which may contamination the firm's product.

On 04/06/09, the bleach and water solution was tested again and once again, the test strip turned (b) (4). When diluted with at least (b) (4) the volume of water, the diluted solution tested at greater than (b) (4) ppm. Mr. Jao stated that he asked his employees to decrease the amount of bleach in the solution after the observation was initially brought to his attention. We informed him that the concentration was too high. We also stated our findings to Mr. Ginsberg and (b) (4).

On 04/08/09, Mr. Ginsberg and (b) (4) stated that the firm is in the process of implementing a system to batch produce the sanitizing solution so an uniform concentration can be achieved. The firm provided us material Safety Data sheets for the cleaners and sanitizers that the firm ordered and plans to use (Exhibit #26). We voiced our concern that sanitizer concentration for food contact and non food contact surfaces should differ. Mr. Ginsberg stated that this concern will be addressed. Once the sanitizers and cleaners arrive, the firm will implement their new cleaning and sanitizing procedures. Correction is promised in two weeks.

OBSERVATION 3

Employees did not wash hands thoroughly in an adequate hand-washing facility at any time their hands may have become soiled or contaminated.

Specifically,

On 04/02/09, an employee was observed cutting open (b) (4) pound plastic bags of sour bears with a box cutter, placing the box cutter back into his pants pocket, throwing the plastic bags in the trash and returning to packing sour bears into plastic containers in the Packaging Department, without changing his gloves or washing his hands. The sour bears are a ready-to-eat food item.

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On 04/06/09, (b) (4) employees placing Snow White Squash Seeds labels on plastic lids were noted touching the food contact surfaces of the lids with bare hands.

Reference: 21 CFR 110.10(b)(3)

Relevance:

Hands should be washed to minimize the possibility of contaminating food and food contact surfaces.

Discussion with Management:

Ms. Cohen stated that employees will be retrained by 04/17/09.

OBSERVATION 4

Failure to provide hand washing facilities at each location in the plant where needed.

Specifically,

The only hand washing sinks in the facility are located in the employee bathrooms. No hand washing sinks were noted in the Packaging Department, Panning Room, Organic Room or Roasting Room where ready-to-eat food products are processed and repacked. These processing areas cover approximately (b) (4) square feet.

Reference: 21 CFR 110.37(e)(1)

Relevance:

Hand washing stations should be conveniently located and available so that employees can readily wash their hands any time they become soiled or might be a vector of contaminating food and food contact surfaces.

Discussion with Management:

Mr. Ginsberg questioned whether the firm's current practice where the employees wear gloves and sanitize their hands is adequate. We stated that sanitizing is not the same as cleaning. Sanitizing does not remove bio-burden. Ms. Cohen stated that she will look into installing additional hand washing sinks in the facility.

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OBSERVATION 5

Failure to wear hair restraints where appropriate.

Specifically,

On 03/31/09, an employee with facial hair was observed packing ready to eat veggie chips into plastic containers in the Packaging Department without a hair restraint for his facial hair.

On 03/31/09, the manager who accompanied us on the walkthrough of the entire facility did not wear a hair restraint for his facial hair. The walkthrough included the Roasting Room and Packaging Department where ready to eat nuts, candy and snacks were being processed and repacked. The same manager was noted in the processing area without a hair restraint for his facial hair on 04/02/09 and 04/06/09.

On 03/31/09, an employee packing ready to eat veggie chips into plastic containers in the Packaging Department failed to wear a hair net effectively in that the hairnet only covered the top of his head and the hair below the hair net was not restrained.

On 04/06/09, (b) (4) employees and a manager in the Packaging Department failed to wear a hair net effectively in that the hairnet only covered the top of their heads and the hair below the hair net was not restrained. (b) (4) of the employees were noted packing ready-to-eat dried berries and chips into plastic containers and (b) (4) employee was noted cleaning in the Packaging Department by the bulk packing line.

Reference: 21 CFR 110.10(b)(6)

Relevance:

Hair restraints should be worn in the processing area by all personnel to prevent hair from contaminating food and food contact surfaces.

Discussion with Management:

Ms. Cohen stated the employees will be retrained on the proper way to wear hairnets and facial hair restraint on by 04/17/09.

OBSERVATION 6

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

Specifically,

On 03/31/09, an uncovered light was noted directly over a hopper filled with unroasted cashews in

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the Roasting Room.

Reference: 21 CFR 110.20(b)(5)

Relevance:

Lights should be shielded over food and food storage and processing areas to minimize the possibility of contaminating food in case the bulbs shatter.

Discussion with Management:

As per Joel Ginsberg, the light over the hopper has been shielded. Correction was verified on 04/08/09.

REFUSALS (JC)

During the current inspection, refusal of photography was encountered several times. Management stated that the company has a strict company policy which does not permit photography in the facility.

GENERAL DISCUSSION WITH MANAGEMENT (JC)

On 04/08/09, the discussion with management was attended by Ms. Mia R. Cohen, Chief Operating Officer; Mr. Joel Ginsberg, Warehouse Manager; (b) (4), Counselor at Law (b) (4); (b) (4); (b) (4); (b) (4) and FDA Investigators Frank Verni, Matthew R. Palo, Sarah A. Wangseng, and Jane Chen. An FDA-483, Inspectional Observations, was issued to Ms. Cohen. See the above section "Objectionable Conditions" for observations noted on the FDA-483 and management's response to each of the observations.

In addition, the following verbal observations were discussed with management during the closing meeting: chocolate was noted on the floor by the dumpster located to the (b) (4); (b) (4) brooms were noted in the panning room between coating pan (b) (4) and polishing pan (b) (4); lights were noted unshielded throughout the warehouse; three holes noted in the walls of the walk-in refrigerator; and an approximately 1/4 inch gap was noted at the bottom of the pedestrian door by the back loading dock.

The chocolate was removed and the brooms removed once the observations were pointed out on 03/31/09. The corrections were verified on 03/31/09. Mr. Ginsberg stated that an order has been placed for shatter proof lights to replace the lights currently in the warehouse. In addition, the three holes noted in the walk-in were sealed with silicone and correction was verified on 04/08/09. Mr. Ginsberg stated that the gap beneath the door will be corrected by the end of next week.

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ADDITIONAL INFORMATION (FV)

During our write-up of the establishment inspection report, the firm issued a new press release (Exhibit #25) due to the expansion of the recall by Setton Pistachio of Terra Bella, Inc. on 04/14/09. The expanded recall now encompasses all quarantined pistachio products being voluntarily held by the firm, except for several products produced with pistachios from the 2007 crop and raw in-shell pistachios, which are both not included in the expanded recall. Recall notices were sent to direct consignees starting that evening.

SAMPLES COLLECTED (JC)

Samples (b) (4) and (b) (4), consisting of (b) (4) environmental swabs and sponges were collected throughout the processing facility. In addition, finish product samples (b) (4) and (b) (4) was also collected.

Sample (b) (4) consist of:

(b) (4) environmental swabs and sponges were collected randomly throughout the facility collected on 04/02/2009.

Sample (b) (4) was a continuation of (b) (4) and consist of:

(b) (4) environmental swabs and sponges were collected randomly throughout the facility collected on 04/06/2009.

Sample (b) (4) consists of:

20 units of DELUXE RAISIN NUT MIX labeled in part; (b) (4)

(b) (4)
The sample was collected

randomly from the dealers stock.

Sample (b) (4) consists of:

20 units of WAIST FRIENDLY MIX labeled in part; (b) (4)

(b) (4)

. The sample was collected randomly from the dealers stock.

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The samples were sent to the FDA Northeast Regional Laboratory for salmonella analysis (Attachments # 11-14).

VOLUNTARY CORRECTIONS (JC)

Please refer to the “**Objectionable Conditions and Management's Response**” section of the report for the firm's voluntary corrections during the current inspection.

EXHIBITS COLLECTED (JC)

1. Setton Farms Product Catalog (6 pages).
2. Setton Farms Product Catalog (16 pages).
3. Setton Farms Product Catalog (20 pages)
4. Setton's International Foods, Inc. majority ownership (1 page).
5. Setton International Foods, Inc. Organizational Chart, dated April 1, 2009 (1 page).
6. Setton International Foods, Inc. Commack Facility Layout (1 page).
7. Setton International Foods, Inc. Commack Facility Layout with labeling of rooms (1 page).
8. Setton International Foods, Inc. final product labels from initial recall (17 pages).
9. Setton International Foods, Inc. Food Allergen Control Plan (6 pages).
10. Setton International Foods, Inc. Daily Metal Detection Sensitivity Test Sheet (1 page).
11. Setton International Foods, Inc. Initial Scale Weight Check Log (1 page).
12. Setton International Foods, Inc. Master Cleaning Schedule Procedures (4 pages).
13. Setton International Foods, Inc. Equipment Cleaning Procedures (5 pages).
14. Setton International Foods, Inc. Master Cleaning Schedule Log for February 2009 (6 pages).
15. Informative Bulletin on ^{(b) (4)} (2 pages).
16. Setton International Foods, Inc. Internal Preventative Pest Control Procedures (2 pages).
17. Setton International Foods, Inc. ^{(b) (4)} Report for 2/19/09 and 3/13/09 (2 pages).
18. Setton International Foods, Inc. External Preventative Pest Control Program, License and Record (3 pages).
19. Setton International Foods, Inc. ^{(b) (4)} Log (1 page).
20. Setton International Foods, Inc. Product Recall Procedure (5 pages).
21. Bill of Lading for shipment of recalled pistachios to Setton International Foods, Inc. (8 pages)
22. Setton International Foods, Inc. Quarantined Products not in Recall 04/02/09 (2 pages).
23. Pistachio Shipments from Setton Pistachio of Terra Bella, Inc. to Setton International Foods, Inc. (9 pages).
24. Setton International Foods, Inc. Press Release dated April 3, 2009 (3 pages).
25. Setton International Foods, Inc. Press Release dated April 6, 2009 (3 pages).

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26. Material Safety Data Sheets for cleaning and sanitizing products planned to be used at the facility (4 pages).

ATTACHMENTS (JC)

1. FDA-482, Notice of Inspection, dated 3/31/09 issued to Mia R. Cohen, Chief Operating Officer (1 page).
2. FDA-482, Notice of Inspection, dated 04/02/09 issued to Mia R. Cohen, Chief Operating Officer (1 page).
3. FDA-484, Receipt for Sample, dated 04/08/09 issued to Mia R. Cohen, Chief Operating Officer (2 pages).
4. FDA-484, Receipt for Sample, dated 04/08/09 issued to Mia R. Cohen, Chief Operating Officer (2 pages).
5. FDA-483, Inspectional Observations, dated 04/08/09 issued to Mia R. Cohen, Chief Operating Officer (3 pages).
6. Email from Canadian Food Inspection Agency (6 pages).
7. Description of sponges and swabs collection location for (b) (4) (4 pages).
8. Layout of sponges and swabs collection location for (b) (4) (1 page).
9. Description of sponges and swabs collection location for (b) (4) (2 pages).
10. Layout of sponges and swabs collection location for (b) (4) (1 page).
11. Collection Report for (b) (4) (3 pages).
12. Collection Report for (b) (4) (3 pages).
13. Collection Report for (b) (4) (3 pages).
14. Collection Report for (b) (4) (3 pages).

Jane Chen, Investigator

Frank Verni, Investigator

Matthew R. Palo, Investigator

Sarah A. Wangseng, Investigator