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Establishment Inspection Report

Setton Pistachio of Terra Bella, Inc.
Terra Bella, CA 93270

FEI: **2939582**
EI Start: 03/26/2009
EI End: 04/30/2009

SUMMARY

This comprehensive compliance inspection of a pistachio, cashew and mixed nut processor and nut product repacker under Field Accomplishment and Compliance Tracking System (FACTS) assignment ID # 1036572, was conducted as an emergency follow-up to an e-mail received by the US FDA San Francisco District (SAN-DO) from US FDA Center of Food Safety and Nutrition (CFSAN) which alerted SAN-DO about a PowerPoint presentation (Attachment A) and phone call from (FEI: 1000036861) Kraft Foods, Inc., Northfield, IL. The Kraft Food, Inc. informed CFSAN that *Salmonella* was found in samples of their Back to Nature Nantucket Blends trail mix, a product manufactured by (FEI: 1420251) Georgia Nut Company (GNC), Skokie, IL, in 9/2008, 11/2008, and 2/2009. In 3/2009, GNC was making a new product and again found *Salmonella*. The only ingredient in common with the Nantucket Blend was pistachios. Kraft then began having samples of pistachios analyzed and found two cases of pistachios contaminated with *Salmonella* which were manufactured by and received from Setton Pistachio of Terra Bella, Inc., Terra Bella, CA.

Based on the CFSAN information, SAN-DO initiated an assignment to inspect Setton Pistachio of Terra Bella. The Program Activity Code (PAC) and specific Compliance Programs covered during this inspection were 03R856-Pistachio Emergency/Recall, 7303.803-Domestic Food Safety, 7321.005-Domestic and Import Nutrition Labeling and Education Act and General Labeling Requirements and under SAN-DO FY-09 work plans. This was a joint inspection involving the San Francisco District and the California Department of Public Health (CDPH), Food and Drug Branch (FDB).

The previous inspection of this firm conducted on 2/26/2003 was classified Voluntary Action Indicated (VAI). No form FDA 483, Inspectional Observations, was issued. There were some inspection observations pointed out to and corrected by management which included fixing a sanitizer dispenser, correcting employee practices involving street clothes sleeves or rolled up street clothes sleeves touching product, removing a terry cloth towel with loose thread hanging over a conveyor belt above exposed product, and closing an open north loading door. Peeling paint on hoppers and screens as well as uncovered bins of processed product which had splintered wooden bins stacked over them were also pointed out to management who alerted a maintenance employee about the problem.

Covered during the current inspection were the raw and roasted pistachios, raw and roasted cashews, and the nut product repacking operations. The firm was processing pistachios on 3/26/09, but that process was not observed that day. The 3/26/09 pistachio final product was sampled by FDA on 3/27/09. After the initiation of this inspection on 3/26/09, the firm's management said they would stop packaging and halted shipments from their Terra Bella facility. On 3/27/2009, the firm was scheduled to do the following operations: In-shell pistachio sizing, color sorting, hand sorting, kernel hand and color sorting, and kernel roasting (See Exhibit #1). The firm did not package on 3/27/09, but a microbiological kill validation study was being conducted on one of the firm's roasters in which the roasting of pistachios was observed. On 4/30/2009, the firm was observed packaging raw in-shell pistachios into woven bags for export. Between 3/28/2009 and 4/16/2009, no processing

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operations were observed and the firm's management stated that they had not processed any products during that time span.

Records and documents reviewed included but were not limited to the following: product flow diagrams, building schematics, production records, sanitation procedures and records, private laboratory analytical reports, audit reports, pest control procedures & records, product shipping records, ingredient/raw pistachio receiving records, silo records, sanitizer records, allergen program documents, HACCP plan, CCP monitoring records, product inventory records, employee training records, pistachio grower receiving records, recall procedures, on-going pistachio recall information including customer lists and distribution records.

The current inspection found the firm failed to meet all the requirements stated in 21 CFR Part 110, Current Good Manufacturing Practice in Manufacturing, Packing or Holding Food. The firm voluntarily recalled roasted pistachio products and raw shelled pistachios processed on or after September 1, 2008 (including the 2007 crop packed in the 2008 crop year) due to the fact that *Salmonella* was found in environmental swabs and roasted pistachio products by private laboratory and FDA San Francisco District Laboratory analyses. The recall started on 3/30/09 and the firm was holding the recalled product as the product was being returned to them. At end of the inspection, the disposition of the recalled product was unclear.

A form FDA 483, Inspectional Observations, was issued noting the following deviations from 21 CFR Part 110:

- Lack of adequate planned and systematic procedures for taking all actions necessary to prevent food from being adulterated.
- Lack of adequate controls to assure that the roasting process is effective in destroying microorganisms of public health significance.
- Failure to monitor roasting temperatures, the time pistachios were exposed to heat and the depth of the pistachios on the roasting belts as they are processed through the roasters.
- Failure to calibrate the roaster monitoring devices such as temperature monitoring devices, belt speeds of the roaster conveyor belts and the timing device.
- Lack of an effective air flow system to prevent cross-contamination of the finished roasted pistachio and nut products.
- Lack of effective measures to prevent finished roasted ready-to-eat pistachios from being cross contaminated with raw product and allergen ingredients.
- Lack of proper sanitation controls to prevent pistachios from being cross contaminated by conveyor buckets stored exposed to the outside environment.
- Use of infrequently cleaned cloth-like material (that was moist) observed holding braces in the roasting room.
- Dust and debris covered fan blades and guard grill observed in the packaging room where finished roasted ready-to-eat pistachios are packaged.

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The following inspectional observations were not listed on the Form FDA 483, but were discussed with management. In reviewing the lot coding system and production records, errors in the production records were noted which included missing/incorrect dates, missing time, and misidentification of product run, holes were punched through the records which destroyed some information recorded, and there were unexplained lot coding changes. Some laboratory microbiological results had no direct links to the products being tested. There were holes and gaps beneath rollup doors in the warehouse areas. The (b) (4) instrument had no records present to indicate that it had been calibrated. The sanitation records reviewed did not have the sanitizer concentrations listed, did not record the amount of sanitizer used, the concentration of the sanitizer and/or there were no sanitation records. Observed bin cleaning practices noted that employee gloves and scrubbing pads had fallen on the ground during break and later picked up by employees who continued to clean the bins without sanitizing the gloves or scrubbing pads. Foot baths or other sanitizing systems were not present to prevent the movement of pathogens from one area to another area by employees. One of the women's restrooms did not have hot water and were a long distance from the packaging and roasting areas. Also, discussed with the firm's management on 4/14/09 and 4/30/09 was their planned procedure of handling lot and environmental samples that tested positive for *Salmonella*.

The firm refused to allow US FDA investigators the use of a camera to take photographs, refused access to their customer complaint file, and refused to sign affidavits.

Digital photographs were taken by California Department of Public Health, Food and Drug Branch employees which are included in Exhibits # 59 & 92 of this inspectional report and attachments to the collection reports: 501599, 482178, 490163, 482179, 529672 and 489158, .

Ten samples, INV 482178, INV 482179, INV 489157, INV 489158, INV 490162, INV 490163, INV 501599, INV 501600, INV 529672, and INV 531954, were collected during the inspection. Sample INV 482178 environmental swab sub #2 collected on 3/28/2009; Sample INV 489158 environmental swab sub #9 collected on 3/31/2009; Sample INV 490163 environmental swab sub #67 collected on 3/28/2009; and Sample INV 482179, Roasted/Salted Garlic/Onion Pistachios in 25 lb. plastic lined cartons, collected on 3/30/2009 were positive for *Salmonella Montevideo*. These samples matched the serotype and DNA with the private laboratories' isolates that detected *Salmonella*-positives from Setton pistachios. These positive pistachios were samples of roasted pistachios that were originally going to (b) (4) related firms. (b) (4) requires Setton to provide them with *Salmonella* testing certificates on all products shipped to them. Ten documentary samples (501601, 501602, 501603, 501604, 501605, 501606, 501607, 501608, 538400 and 538401) were collected to document interstate commerce for raw in-shell pistachios and seasoning ingredient received, finished pistachio products shipped, and oil stock pistachio by-product shipped.

Management was warned, if corrections were not made, further regulatory/legal actions such as product seizure, injunction and/or prosecution actions could occur, if warranted.

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Management stated they had already corrected or will correct all the FDA 483 observations and the other observations that were discussed with them. Management said they would respond in writing.

Voluntary corrections made included segregating the raw and roasted pistachio operations by rebuilding walls, eliminating false walls, and sealing doorways; a new roof was installed; the firm created a positive air flow system in the roasted pistachio area; dust collecting equipment was placed outside the building; bin cleaning records are now being maintained; drain pipes were placed inside the drains instead of the having them divert runoff directly onto the floor areas; and the firm started a (b) (4) bin multiple testing program for all incoming raw pistachio products to be analyzed by a private laboratory for *Salmonella*, *Escherichia coli*, *Shigella*, Total Plate Count, and Total Coliform with a bin (b) (4) system.

ADMINISTRATIVE DATA

Inspected firm: Setton Pistachio of Terra Bella, Inc.

Location: 9370 Road 234
Terra Bella, CA 93270

Phone: (559) 535-6050

FAX: (559) 535-6089

Mailing address: 9370 Road 234
Terra Bella, CA 93270

E-mail address nlapietra@settonfarms.com

Hours of Operation (b) (4)

FDA-482's issued to Nicolo (NMI) Lapietra (General Manager)
Joshua J. Setton (President/CEO)
Agustin (NMI) Gonzalez, Jr. (Plant Supervisor)

FDA-483's issued to Nicolo (NMI) Lapietra (General Manager)

FDA-484's issued to Nicolo (NMI) Lapietra (General Manager)

Dates of inspection: 3/26/2009, 3/27/2009, 3/28/2009, 3/30/2009, 3/31/2009, 4/1/2009,
4/2/2009, 4/3/2009, 4/6/2009, 4/7/2009, 4/8/2009, 4/9/2009,
4/10/2009, 4/14/2009, 4/15/2009, 4/16/2009, 4/30/2009

Days in the facility: 17

Participants: Larkin R. Buckalew, Investigator
Karen J. Bak, Investigator
Estefania Fernandez, Investigator
Joanne M. Fukuda, Investigator
Terrence Gee, Investigator

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Helen J. Hamaoka, Investigator
Alex G. Kalugin, Investigator
Jennifer H. Rhyu, Investigator
Quynh Strandberg, Investigator
Steven M. Galvez, Investigator

This was a team inspection. The team leader was Investigator Larkin R. Buckalew, San Francisco District Office. Other SAN-DO Investigations Branch personnel participating in this team inspection included the following individuals plus the inspection dates they were at the firm: Fresno Resident Post Investigator Helen J. Hamaoka (present during all the inspection dates); Fresno Resident Post Investigator Karen J. Bak (3/31/2009); Fresno Resident Post Investigator Estefania Fernandez (3/26/2009, 3/27/2009, 3/28/2009 & 3/30/2009); Fresno Resident Post Investigator Joanne M. Fukuda (3/28/2009 & 3/30/2009); Fresno Resident Post Investigator Alex G. Kalugin (3/28/2009 & 3/30/2009); Fresno Resident Post Investigator Steven M. Galvez (3/30/2009); San Francisco District Office Investigator Terrance Gee (3/27/2009, 3/28/2009, 3/30/2009, 3/31/2009, 4/1/2009 & 4/2/2009); San Francisco District Office Investigator Jennifer H. Rhyu (3/27/2009, 3/28/2009, 3/30/2009, 3/31/2009, 4/1/2009 & 4/2/2009); and San Francisco District Office Investigator Quynh H. Strandberg (3/27/2009, 3/28/2009, 3/30/2009, 3/31/2009, 4/1/2009 & 4/2/2009).

The following California Department of Public Health, Food and Drug Branch employees participated in this joint inspection: Benson J. Yee, Chief Emergency Response Unit; Lottie E. Bloxson, Food & Drug Investigator; Amber Barnes, Food & Drug Investigator; Duy Truong, Food & Drug Investigator, and Qinyan (Julia) Zhu, Food & Drug Microbiologist.

The United States Department of Agriculture has an office at the firm site. No USDA Inspectors were present during the inspection. The United States Standards for Grades of Pistachio Nuts is Exhibit #2.

The following subsection was reported by FDA Investigator Hamaoka. There were ten US FDA investigators on this inspection. This inspectional report was written by four FDA investigators. Investigator Rhyu wrote the subsection of the process for the incoming field pistachios to silo storage in the Operations section of this report. Investigator Fernandez wrote the subsections titled, Exhibits Collected and Attachments, of this inspection report. Investigator Buckalew wrote the subsections Summary, Training, Interstate Commerce, Recalls, Objectionable Conditions and Management's Response, Additional Information and parts of Operations, Individual Responsibility, Administrative Data, History, Jurisdiction and Refusal sections of this report. Investigator Hamaoka wrote the Samples Collected, Microbiological, Manufacturing Codes, Complaints, Timeline and parts of Administrative Data, Individual Responsibility, Jurisdiction, Operations, History, Objectionable Conditions and Management's Response, General Discussion with Management, Summary and Refusal subsections of this report.

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Each subsection of this report will identify the Investigators Fernandez, Hamaoka and Rhyu who wrote the related preceding sections of the report. The unidentified sections were written by Investigator Buckalew. Thus, the "I" (first person singular pronoun), my, me and myself, referred to the aforementioned writers, unless noted. The "we," "us" and "our" indicate the various investigators previously mentioned to be present on the inspection days of this report unless noted.

On the afternoon of 3/26/09, FDA Investigators Fernandez and Hamaoka showed their credentials and issued a Notice of Inspection, Form FDA 482, to Nicolo (NMI) Lapietra (General Manager) the most responsible individual of the firm. The FDA investigators were accompanied by Duy (NMI) Truong, FDB Investigator. Within the half hour, Joshua J. Setton, President and CEO of Setton International Foods, Inc. and Setton Pistachio of Terra Bella, Inc., and H. Lee Cohen, Production Manager of Setton International Foods, Inc. arrived from New York. We displayed our credentials to them. Later during the inspection we displayed our credentials to Jeffrey J. Gibbons (Plant Manager), Frank G. Aguilera (Quality Supervisor) and Octavio (NMI) Campos (Production Supervisor).

During most of this inspection, the California Department of Public Health, Food and Drug Branch (FDB) Investigators who are noted on the chart on page 8 were also present with FDA.

On 3/27/09, the inspection team was joined by four more US FDA Investigators from the San Francisco District Office. The FDA investigators were: Larkin R. Buckalew, Terrence Gee, Jennifer H. Rhyu and Quynh Strandberg. They issued an FDA 482 Notice of Inspection and displayed their credentials to Joshua J. Setton (President/CEO). FDB Investigators present with FDA on that inspection day were: Benson J. Yee (FDB Supervisor), Amber Barnes (FDB Investigator) and Q. Julia Zhu (FDB Research Scientist). Exhibit #3 shows the FDB and FDA personnel present on the afternoon meeting with the firm's upper management.

Mr. Joshua Setton was present with us on 3/26-30/09. His son-in-law, Harris Lee Cohen (Production Manager of Setton International Foods, Inc., Commack, NY) was present with us on 3/26-4/3/09 & 4/14-16 & 30/09.

FDA Investigators Joanne M. Fukuda and Alex G. Kalugin were present at the firm on 3/28/09 and they issued another FDA 482 and displayed their credentials to Joshua J. Setton (President/CEO). On 3/29/09 FDA Investigator Steven M. Galvez joined the team. He issued an FDA 482 and displayed his credentials to Agustin (NMI) Gonzalez, Jr. (Plant Supervisor) as Mr. Setton and Mr. Lapietra were unavailable.

On 3/30/09, an FDA 482c Notice of Inspection-Request for Records with the 414 Attachment Records To Be Made Available Pursuant To Sections 414 and 704 of The Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 350C and 374) was issued to Joshua J. Setton (President/CEO) at 11:11 am. The attachment was read to him and to his management staff and his attorneys.

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Exhibit #4 indicates the personnel in attendance during this gathering. FDA credentials were again displayed by each of the FDA investigators, Larkin R. Buckalew, Helen J. Hamaoka, Estefania Fernandez, Terrence Gee, Jennifer H. Rhyu, Joanne M. Fukuda, Alex G. Kalugin and Steven M. Galvez. The firm's attorneys present were, (b) (4) (Attorneys at Law with (b) (4)). Mr. (b) (4) recorded our credential numbers. Mr. (b) (4) requested the identity of the FDA trainees present. FDA Investigator, Quynh Strandberg, arrived during this time and she issued another FDA 482c with the 414 Attachment and displayed her credentials to Joshua J. Setton. Investigator Buckalew explained the FDA 482c and 414 Attachment to Mr. Setton. Also, Mr. Setton was provided with a copy of Regulatory Procedures Manual, Section 10-4 Inspection of Food Records-Sections 414(a) and 704(a) (Attachment K), which Investigator Buckalew reviewed with him with the aforementioned individuals present.

The next day (3/31/09) FDA Investigator Karen J. Bak was present at the firm and another FDA 482c with the 414 Attachment were issued and her credentials displayed to Joshua J. Setton (President/CEO).

On 4/15/09 another 482c with 414 Attachment was issued to Nicolo (NMI) Lapietra (General Manager) per instructions from FDA headquarters.

The following personnel were present during the inspection on the following days.

NAMES	TITLE	3/26	3/27	3/28	3/30	3/31	4/1	4/2	4/3	4/6	4/7	4/8	4/9	4/10	4/14	4/15	4/16	4/30	
Larkin R. Buckalew	Lead FDA Investigator																		
Helen J. Hamaoka	FDA Investigator																		
Estefania Fernandez	FDA Investigator																		
Terrence Gee	FDA Investigator																		
Jennifer H. Rhyu	FDA Investigator																		
Quynh Strandberg	FDA Investigator																		
Joanne M. Fukuda	FDA Investigator																		
Alex G. Kalugin	FDA Investigator																		
Karen J. Bak	FDA Investigator																		
Steven M. Galvez	FDA Investigator																		
Benson J. Yee	FDB Supervisor																		
Lottie E. Bloxsom	FDB Investigator																		
Duy Truong	FDB Investigator																		
Amber Barnes	FDB Investigator																		
Qinyan Julia Zhu	FDB Research Scientist																		
Eric Maddox	FDB Investigator																		
Nicolo (NMI) Lapietra	Gen. Mgr of Setton																		
Joshua J. Setton	President/CEO																		
H. Lee Cohen	Prod. Mgr of NY facility																		

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There was a break from 4/19-29/09 in the inspection to organize the inspectional teams' findings and compose the FDA 463a-Affidavits and 483-Inspectional Observations.

This firm has USDA personnel on-site when the firm is actively processing. They certify that domestic shipments from Setton are below 5 ppb Aflatoxin. On the first day of the inspection Investigators Hamaoka and Fernandez inquired if USDA was present. We were told by management that USDA was not currently present. We requested that they (the firm's management) let us know when the USDA personnel arrived. During the inspection, we did not meet any USDA personnel. USDA was not present on the last day of the inspection when Investigators Buckalew and Hamaoka inquired and requested to talk to any USDA personnel present.

Due to the break in the inspection, on 4/30/09 a FDA 482c with 414 Attachment was issued to Nicolo (NMI) Lapietra with H. Lee Cohen, Jeffery J. Gibbons, ^{(b) (6)} Octavio (NMI) ^{(b) (6)} and Frank G. Aguilera present. Mr. Cohen said they would each read the affidavits, make corrections, initial the corrections and would state that they had read the affidavits but would not sign them. FDA Investigator Buckalew and I witnessed each of them reading the affidavits, making corrections and initialing the corrections. Mr. Cohen said they would not sign the affidavits because of their company's policy. I asked Mr. Lapietra to sign the FDA 484 Receipt for Samples and Mr. Cohen gave permission for Mr. Lapietra to sign the FDA 484 Receipt for Samples. For information on the FDA 483 issued and items discussed on 4/30/09, see the sections below titled, Objectionable Conditions and Management Response and Discussion with Management, of this inspection report (on page 64).

Listed below are references of organization and abbreviations that this report and its tables/spreadsheet are referring to:

^{(b) (4)}

CDPH	California Department of Public Health
CFSAN	Center of Food Safety and Nutrition
CCP	Critical Control Point
COA	Certificate of Analysis
DFA	American Council for Food Safety & Quality (ACFSQ) or aka DFA of California (DFA)
FDA	Food and Drug Administration
FDB	Food and Drug Branch
GNC	Georgia Nut Company
HACCP	Hazard Analysis and Critical Control Point
IS	Interstate
Kraft	Kraft Foods

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(b) (4)

(b) (4)

SAN-DO San Francisco District Office (of FDA)

Setton Setton Pistachio of Terra Bella, Inc.

(b) (4)

(unless otherwise noted)

SOP Standard Operation Procedure

SSOP Sanitation Standard Operation Procedure

(b) (6)

414 Attachment Records to be Made Available Pursuant to Sections 414 and 704 of the Federal Food, Drug, and Cosmetic Act (21 USC 350c and 374)

Kernels, shelled and meats are all the same product

HISTORY

This firm was formerly Setton Pistachio Company, Inc. located in Madera, CA. The firm moved to its current location in 1995 and the firm's legal name was changed to Setton Pistachio of Terra Bella, Inc. Setton Pistachio of Terra Bella, Inc. is a State of California corporation, number C1935058, incorporated on July 21, 1995 (See Exhibit #5 pages 1-8). Attachment B is a copy of the Secretary of State California Business Portal for Setton Pistachio of Terra Bella, Inc.

The firm's headquarters and sister repacking food firm is Setton International Foods of Brooklyn, Inc. (dba Setton International Foods, Inc.) 85 Austin Blvd., Commack, NY 11725 (FEI: 2433583) which is a State of New York corporation, number 879209, incorporated on January 4, 1971 (See Exhibit #6 pages 1-7). Page 7 shows that Setton International Foods, Inc. was dissolved on January 4, 1971. On the New York State Department of State, Division of Corporations website (Attachment C) shows the active corporate status of the firm located at 85 Austin Blvd., Commack, NY 11725 which is Setton International Foods of Brooklyn, Inc and which Joshua Setton is listed as the CEO. The inspected firm appears to use the former corporate name in their records we observed and on their business cards presented to us.

Since the last inspection, the firm currently has an on-going voluntary recall involving

1) roasted pistachio products and

2) raw shelled (kernels) pistachios that are not roasted prior to retail sale

manufactured from September 1, 2008 through March 25, 2009, including the 2007 & 2008 crop years processed during that time period, because *Salmonella* was found in environmental swabs and roasted pistachio products collected based on private laboratory and FDA San Francisco District Laboratory analysis (See Exhibit #7-13 and Attachment D,

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E, F, G, H, I & J). The raw in-shell pistachios were not recalled.

The firm operates (b) (4) hours a day and (b) (4) There is a (b) (4) for product processing (b) (4) (b) (4).

About (b) (4) full time employees work at the firm during the peak season and around (b) (4) employees work there during the remainder of the year. The firm's covered area (processing and warehouse storage space) is about (b) (4) square feet, (Exhibit #15).

The previous inspection of the firm was discussed above under the heading, Summary (on page 2). Changes since the previous 2003 inspection, include a new finishing room for processing raw pistachios; a new hand-sort room; an (b) (4) a new building addition; additional warehouse storage space added; and a new roof and sheller room.

(b) (3) (A)

The most responsible person at the firm's Terra Bella, CA site is General Manager, Nicolo (NMI) Lapietra who maintains an office there and all correspondence for Mr. Lapietra should be sent to the 9370 Road 234, Terra Bella, CA 93270 address (telephone # 559-535-6050).

The most responsible official for the Setton Pistachio of Terra Bella, Inc., Terra Bella, CA and the Setton International Foods, Inc., Commack, NY operations is Joshua J. Setton, President/Chief Executive Officer (CEO), who maintains an office in Commack, NY, and all correspondence for Mr. Setton should be sent to the 85 Austin Blvd., Commack, NY 11725 address (telephone # 631-543-8090).

Since 1995 the firm has been an American Council for Food Safety & Quality (ACFSQ) (formerly DFA of California), Fresno, CA member in which SAN-DO/LOS-DO have a partnership in conducting inspections and the sharing of the number inspections. The ACFSQ/DFA is an industry related business that provides inspection and testing services to food producing firms. Dried fruit and nut processors can voluntarily become a member of DFA and the membership dues include inspection and testing services. The inspections are unannounced and are GMP type inspections covering 21 CFR 110 and they are currently conducted 3 times a year. Under this partnership, when ACSFQ/DFA becomes aware of any situation or product in one of its member facilities that represents a public health hazard, ACSFQ has agreed to immediately notify FDA. To reduce inspectional duplication and efforts FDA conducts audit inspections of ACSFQ/DFA member firms and has yearly partnership meetings with ACFSQ/DFA that include sharing of inspection observations. The last FDA inspection of Setton Pistachio was in 2003 and it was one of the audit

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inspections under the partnership. This firm is a member of ACFSQ/DFA and has been more actively inspected by them under the ACFSQ/SAN-DO/LOS-DO Partnership, Exhibit #16.

The firm also provided us with their inspection audits performed by (b) (4) (b) (4) which is required by their customers, (b) (4) and (b) (4) Exhibit #17. The dates of the last three years of the third party audits are listed in Exhibit #18.

TIMELINE OF SOME OF THE EVENTS RELATED TO THIS INSPECTION:

This subsection was compiled and reported by Investigator Hamaoka (with assistance from FDB Investigator Bloxson). It is not all inclusive regarding the all of the events occurring in this extensive investigation that involved many other agencies, departments and districts. Please note that the occurrence times noted for some of the events are not exact, they may reflect when I (not the complete inspection team) heard of the event. The time line for events from 10/9/08 through 3/17/09 was compiled from the records that were provided by the firm's management.

10/2008

- o Firm's management informs us that in October of 2008 (b) (4) increases the amount of sample subs to submit to (b) (4) for *Salmonella* analysis.

10/9/08

- o Firm submits pistachio sample with PO # (b) (4) (relates to FMO/Lot 2818CO3 LgB-2) to (b) (4) Exhibit #19 page 5.

10/13/08

- o (b) (4) receives sample related to PO# (b) (4) (firm's management says this PO # indicates sample is from FMO/Lot 2818CO3 LgB-2 which was confirmed with PO# (b) (4) on Setton records) to be analyzed for *Salmonella*, Exhibit #19 page 5, 7 & 8.

10/21/08

- o (b) (4) COA dated 10/21/08 indicating PO# (b) (4) that relates to FMO/Lot 2818CO3 LgB-2 is positive for *Salmonella*, Exhibit #19 page 9.

10/22/09

- o (b) (4) Analytical Report with report date 10/27/08 shows sample # (b) (4) with Reference # (b) (4) Roasted/Salted Pistachios with sample date of 10/22/09 was sampled, Exhibit #19 page 11.

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10/24/08

- About (b) (4) environmental swabs are analyzed for *Salmonella* by (b) (4) laboratory and are negative, Exhibit #24.

10/27/08

- About (b) (4) environmental swabs are analyzed for *Salmonella* by (b) (4) laboratory and are negative, Exhibit #25.
- (b) (4) laboratory report date of 10/27/09 indicates sample with sample date of 10/22/08 (above) from Setton is positive for *Salmonella*, Exhibit #19 page 11. (b) (4) gave the sample reference # (b) (4) and sample # (b) (4) Setton now has two positives for same FMO/lot.
- (b) (4) analysis date indicating that raw pistachios with reference # (b) (4) and sample (b) (4) that was sampled on 10/22/08 (on same day as roasted product above) is negative for *Salmonella*, Exhibit #26.

10/28/08

- About (b) (4) environmental swabs are analyzed for *Salmonella* by (b) (4) laboratory and are negative, Exhibit #27.

10/30/08, 11/6/08, & 11/17/08

- Five samples of pistachios were analyzed for *Salmonella* by (b) (4) laboratory and are negative, Exhibit #28.

11/12/08 & 11/17/08

- Three non-commodity samples (snake carcass & cat droppings) are analyzed for *Salmonella* by (b) (4) laboratory and are negative, Exhibit #29.

1/8/09

- (b) (4) COA dated 1/8/09 indicates (firm's management says related to FMO/Lot 3478B14LgB-2R which was confirmed with PO# (b) (4) sample submitted under PO# (b) (4) is positive for *Salmonella*, Exhibit #20 page 3.

1/23/09

- About (b) (4) environmental swabs are analyzed for *Salmonella* by (b) (4) laboratory and are negative, Exhibit #30.

1/28/09

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- About (b) (4) environmental swabs are analyzed for *Salmonella* by (b) (4) laboratory and are negative, Exhibit #31.

2/12/09

- (b) (4) COA dated 2/12/09 indicates (firm's management says related to FMO/Lot 0418W/M which was confirmed with PO# (b) (4)) sample submitted under PO# (b) (4) is positive for *Salmonella*, Exhibit #21 page 5.

3/12/09

- (b) (4) COA dated 3/12/09 indicates (firm's management says related to FMO/Lot 0548B06 Lg-1 which was confirmed by PO# (b) (4) (b) (4)) sample submitted under PO# (b) (4) is positive for *Salmonella*, Exhibit #22 page 5.
- (b) (4) COA dated 3/12/09 indicates (firm's management says related to FMO/Lot 0578 W/M which was confirmed by PO# (b) (4)) sample submitted under PO# (b) (4) is positive for *Salmonella*, Exhibit #23 page 7.

3/17/09

- About (b) (4) environmental swabs are analyzed for *Salmonella* by (b) (4) laboratory and are negative, Exhibit #32.

3/24/09

- (b) (4) audit (Attachment A, page 7) at Setton Pistachio of Terra Bella, Inc. with their issuance of their Summary of Issues at Setton, (Exhibit #39).

3/24/09

- SAN-DO received notification from CFSAN recall division about a conference call with Kraft. Kraft presented FDA with their concerns stemming from their routine product testing detecting *Salmonella* in roasted pistachios from Setton.

3/25/09

- Kraft Foods and the Georgia Nut Company voluntarily recall their Back to Nature Nantucket Blend trail mix related to the positive lot that originated from Setton.

3/26/09

- Conference call with CFSAN, SAN-DO, Office of Regulatory Affairs-Recall and Setton's management regarding their customer's (Kraft) concerns was made. Setton's management talked about voluntarily recalling some of the pistachio

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- shipments, mainly those related to the one that went to their customer, Kraft Foods, Georgia Nut Company (GNC) and (b) (4).
- FDA SAN-DO and California Department of Public Health (CDPH) Food and Drug Branch (FDB) investigators began an inspection at Setton.
 - The firm's management said only 3 lots from FMO 3088 should be involved in the recall. Setton provided us with the records of three lots from FMO 0388 that went to Georgia Nut Company (Lots: 31128 R/S-2018, 31218 R/S-2018 and 31518 R/LS-2018) and (b) (4), Exhibit #88.
 - The firm was aware of its customer's (Kraft Foods) voluntary recall and the recall was related to their firm's pistachios. Setton's management provided Investigator Fernandez and I with 2 voluntary recall notification copies: 1) Kraft Food's voluntary recall notification (it appears to be from Kraft's website). 2) FDA's Recall--Firm Press Release titled Back to Nature Foods Company Conducts Nationwide Recall of Nantucket Blend Trail Mix Containing Pistachio Nuts Because of Possible Health Risk dated 3/25/09, Exhibit #33.
 - Mr. Joshua Setton said they plan to utilize (b) (4) sterilization on all finished product. They will stop all domestic distribution of pistachios (later, it was found the firm was shipping raw in-shell pistachios internationally). They will now test all loads going to domestic customers. I asked how many positives they had in their pistachios, Mr. Gibbons said they had 6 positive (one was a dead DNA) test results. The firm's management said they had already scheduled a consulting firm to conduct a validation study on their roasting processes and (b) (4) of (b) (4) would be at their firm tomorrow.

3/27/09

- The inspectional team was joined by additional investigators from the SAN-DO district office and from CDPH FDB who assisted with the sampling, trace backs, GMP inspection and record review.
- The firm's management said they have hired a consulting firm to establish a scientifically valid sampling protocol for their finished product *Salmonella* sampling.
- (b) (4) COA dated 3/27/09 indicates (b) (4) environmental swab samples that were received on 3/25/09 and analyzed by (b) (4) are negative for *Salmonella*. COA notes swabs were abnormal due to elevated temperature, Exhibit #34. Also, we were informed that (b) (4) collected the first (b) (4) environmental samples but these were analyzed by (b) (4).
- California Department of Public Health releases a News Release on Recalled Pistachios, Attachment L.
- Thirty-one (31) environmental swabs and 2 finished pistachio products (packaged on 3/25 & 26/09 by Setton) were collected and sent to the FDA SAN-DO laboratory. 3/26/09 was the last day the firm packaged finished pistachio products

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for domestic sale. See FACTS INV 501599, 490162 and 189157 collection reports, attached to this inspection report. For more information see the subsection below titled, Samples Collected, of this inspection report (on page 87).

3/28/09

- The SAN-DO and CDPH FDB inspection team collected about 165 environmental samples at the firm. See FACTS INV 482178 and 490163 collection reports, attached to this inspection report. For more information see the heading below titled, Samples Collected, of this inspection report (on page 87).
- A part of the inspection team conducts dry-run of the facility. The firm stopped packaging operations after 3/26/09.
- Mr. Cohen informs us that calls are going to their New York facility and they need to come here since they (Mr. Setton and him) are in Terra Bella, CA. We inform him that they have pistachios out in the marketplace and they are responsible for the wholesomeness of those products.
- (b) (4) COA dated 3/28/09 indicates (b) (4) environmental swab samples that were received on 3/26/09 and analyzed by (b) (4) are negative for *Salmonella*, Exhibit #35.

3/30/09

- FDA 482c Notice of Inspection-Request for Records with the 414 Attachment issued to Mr. Setton (President/CEO).
- Two more finished product samples are collected by the FDA/FDB inspection team. See FACTS INV 482179 and 529672 collection reports, attached to this inspection report. For more information see the heading titled, Samples Collected, of this inspection report below (on page 87).
- A FDA/CDPH conference call with firm was held discussing the scope of the product recall. Later the company, Setton Pistachio of Terra Bella, decides to recall certain bulk roasted in-shell and roasted shelled pistachios that were processed on three pieces of shared equipment (Bulk Line (b) (4) New Building Transfer Hopper and South Sort Room) of its 2008 crop, (Attachment #D page 1 and Exhibit #85 page 2).

3/31/09

- 57 environmental subs were collected by the FDA/FDB inspection team. See FACTS INV 489158 collection report, attached to this inspection report. For more information see the heading below titled, Samples Collected, of this inspection report (on page 87).
- (b) (4) Consultant introduces himself to the inspection team and is assisting the firm on their recall of product processed on shared equipment.

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- The inspection team requests the voluntary recall information including the complete distribution list, recall letter, labels and information to complete Voluntary Recall-Attachment A & B.
- Mr. Cohen tells the inspection team that the firm is dealing with requests from both our upper management and us, and there are too many requests. The inspection team limits its requests, so the firm can concentrate on their voluntary recall.
- Kraft and Georgia Nut Company expands the recall to include any Planters and Back to Nature products that contain Setton pistachios.

4/1/09

- Inspection team has conference calls with FDA, SAN-DO and CDPH/FDB. The inspection team is tasked with finding out how the firm supports their three shared pieces of equipment justification for the scope of their voluntary recall. We make this request to Mr. Cohen.
- (b) (4) tells the inspection team that the firm's personnel cross contaminated their microbiological samples. He says during his interview with employees the same tray table, scissors and cart were used for un-roasted and roasted pistachios during sample collections.

4/2/09

- Part of the inspection team begins a dry run of the pistachio process, but it was interrupted. The dry-run from the incoming field pistachios to the silos was completed.
- One environmental sample of the firm's rinse water that is used to clean bucket conveyors was sampled. See FACTS INV 501600 collection report, attached to this inspection report. For more information see the heading titled, Samples Collected, of this inspection report below (on page 88).

4/3/09

- Mr. Frank G. Aguilera (Setton's Quality Supervisor) informs the inspection team he is not allowed to talk to us.
- Setton is requested to provide us with the justification and supporting documents they used to exclude from the recall lots of product that were not run on the shared equipment.
- A dry run at the oil roaster is conducted by part of the inspectional team.
- We inquired about our earlier request to meet with them to discuss their justification for the scope of the recall. When we inquired about this request, (b) (4) (b) (4), representing Setton as a consultant implied that they were waiting on us. I had informed him we had made our request that morning and that by mid-morning after waiting I checked with Ms. (b) (6) (b) (6) (Office Clerk). She informed me (after she checked with Setton's management) that there was a delay because of camera problems. At the end of the

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day, Mr. Campos and Mr. (b) (4) gave us a presentation on the firm's justification for excluding from their recall the pistachios that were not run on shared equipment. Mr. (b) (4) covered the sanitation, HACCP and microbiological presentation. Mr. Campos filled in the production side of the presentation in the presence of Mr. (b) (4)

- After questioning the firm's management on their records, procedures and on practices we had observed, the inspection team determined that the firm's rationale for their voluntary recall based on shared equipment was deficient. We identified potential cross contamination issues, a lack of roaster validation designed to address microorganisms of public health significance, a lack of controls at the roasters, and microbiological sampling/testing and sanitation practices that existed.
- The firm's sister firm, Setton International Foods, Inc., issues a press release for a voluntary recall on several lots of pistachio kernel products.

4/4/09

- FDA sample INV 482178 sub 2 (overflow water funnel from dewatering screen) is positive for *Salmonella*.
- FDA sample INV 490163 sub 67 (roller-sorter [sizer] is in suspect status).

4/5/09

- Setton is notified of the two positive environmental samples by SAN-DO district director.

4/6/09

- Inspection team is informed that the firm is going to be voluntarily expanding its recall to include 2008 pistachio crop. Mr. (b) (4) said the estimated amount of the product recalled is about (b) (4) lbs. Attachment D pages 2-5 shows this voluntary recall.
- Isolate (related to order #(b) (4) or (b) (4) Reference #(b) (4) stored at the (b) (4) (b) (4) is being sent to FDA Arkansas Regional Laboratory, Jefferson, AR 72079. See FACTS collection reports INV 531954 and DOC 501602 attached to this inspection report. For more information see the heading below titled, Samples Collected, of this inspection report (on page 87).
- The three isolates from the (b) (4) are to be shipped to FDA Arkansas Regional Laboratory, Jefferson, AR 72079. See DOC 538400 for 2 of the three isolates. (For more information see the heading below titled, Samples Collected, of this inspection report (on page 87). For these two isolates, the firm has the related finished products on hold. Thus, IS of (b) (4) pistachios was documented. Since the related finished product for the third isolate went to Hong Kong, China, no FACTS sample was created.

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- FDA sample INV 482179 of Garlic/Onion flavored finished roasted/salted pistachios is positive for *Salmonella*.
- FDA sample INV 489158 sub 9 (air line hose) is positive for *Salmonella*.
- Inspectional team requests a copy of the firm's voluntary recall letter but is informed later in the day that Setton's management in New York is still reviewing it.

4/7/09

- SAN-DO SCSO notifies Setton of the two aforementioned positive samples results.
- The inspectional team continues to request the voluntary recall letter for the expansion of the recall to include 2008 crop and Mr. (b) (4) continues to say it is in New York being reviewed.
- Mr. Aguilera provides copies of confined space entry permit records as silo cleaning records (Exhibit #36). He previously told the inspection team that the firm did not maintain records of cleaning silos. These records are created and signed before entry into the silos acknowledging the safety checks, equipment, personnel entering, attendant to the personnel and that safety procedures are in place. There were no records verifying that the silos were adequately cleaned and proper levels of sanitizer were used in any cleaning.

4/8/09

- Setton's attorney says the voluntary recall letter for the expanded recall was provided to SAN-DO FDA John Liu. The recall letter to expand the recall beyond shared equipment is in Attachment D pages 2-5. The recall letter includes 2008 pistachio crop. The firm's customer recall notice states the date of 4/7/09 (Attachment I) and the firm's recall notice on their web site is dated 4/6/09 (Attachment D pages 2-5).
- Inspection team requests a complete list of customers under the expanded recall.
- Mr. Campos provides an affidavit that the positive *Salmonella* shipment that went to Kraft in October was returned and re-roasted prior to being blended with other pistachio products and distributed, Exhibit #19 page 13. Kraft says this shipment came in without a COA. Thus, they put it on hold. Setton says it was shipped on a waiver at the request of Planters Lifesavers (Kraft).
- (b) (4) informs the team (he acknowledged at the request of Mr. Lapietra) that there are three more positive isolates being sent to the FDA laboratory in Arkansas from (b) (4). These were from finished products sampled by the firm on 3/27/09. These were not from the same product or lots the FDA sampled. The firm also had a composite of 3 lots sent to (b) (4) laboratory that was also positive for *Salmonella*, see more information in header, *Microbiological-Four Positive Finished Products Sampled by the Firm After Initiation of the Inspection* on page 59.

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4/9/09

- Records show pistachios from crop year 2007 were packaged in the 2008 pistachio crop year. (The firm began receiving the 2008 pistachio crop on (b) (4) and began processing the 2008 crop on (b) (4) Exhibit #38).
- Mr. Campos says that all silos were emptied on (b) (4) and there is very little carry over of the 2007 pistachio crop.
- Mr. Campos later tells us the last day hand-sort for the 2007 crop is (b) (4). He provides us with copies of records (Exhibit #37) to indicate these were the last days that 2007 crop was package on the various listed packaging lines. (Later the inspection team finds some of these are incorrect).
- Inspection team requests the current and past month's inventory of 2007 crop. Firm's management says that they could not give us a physical inventory since most of it is currently under fumigation. They gave us an estimate of (b) (4) pounds of 2007 pistachio crop still in existence as of 4/9/09.
- When the inspection team asked for a list of the firm's corrective actions taken since the initial week of the inspection, Mr. Aguilera provided us with copies of the (b) (4) audit performed on the week of 4/24/09 with their (Setton's) corrective actions to each of the (b) (4) comments, Exhibit #39. This (b) (4) audit was requested earlier (with other 3rd party audits) during our review of records. At that time we were informed (b) (4) did not leave anything. Mr. Aguilera said there would be separation of raw and roasted and he is working with (b) (4) on a SSOP and microbiological sampling program.

4/10/09

- SAN-DO SCSO informs Setton that the 3 enviromentals collected by the team were positive for *Salmonella montevideo*.
- The firm's New York firm is inspected and samples are collected.

4/14/09

- Mr. Cohen tells the inspectional team about their remediation procedures and his meeting with the industry groups.
- The firm's sister firm, Setton International Foods, Inc, issues a press release titled Setton International Foods, Inc., Expands Voluntary Nationwide Recall of Pistachios Due to Possible Health Risk. This press release notes that voluntary recall expands the initial 4/3/09 recall by Setton International Foods, Inc.

4/15/09

- A FDA 482c Notice of Inspection-Request for Records and 414 Attachment are issued to Mr. Lapietra (General Manager) in the absence of Mr. Setton.

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- For the 2007 crop, (b) (4) was when the first load of 2007 crop was received by the firm and (b) (4) was the first processing day of the 2007 crop.
- For the 2008 Crop, (b) (4) was when the first load of 2008 crop was received by the firm and (b) (4) was the first processing day of the 2008 crop in facility at the hand-sort operation. According to Mr. Campos (b) (4) was last day that 2007 crop year was packed. During the inspection team records review, later dates than (b) (4) were found on some of the packaging lines. (On 4/16/09 it was found that an employee tends to record the incorrect year and/or flips the day and month on the records. Thus, what was previously reported from the inspection team for each packaging line is questionable.)
- Mr. Campos provides us with the amounts of 2007 crop year currently in their warehouse: (b) (4) lbs of finished products (in their warehouse) and (b) (4) lbs of WIP (work in process) (in bins in firm's cold storage) of 2007 crop. He said he could not give us the amount in pounds under fumigation.
- Mr. Cohen tells the inspection team that the expanded recall includes the shipments after August 2008 (Attachment D pages 2-5) and he does not understand the reason for expanding the recall further. It was explained by FDB and FDA that their voluntary recall is not capturing all suspect 2007 crop year pistachios packed during the 2008 crop year. We had to explain that their recall letter and response form does not adequately present this information to his customers. Mr. Cohen acknowledged this.

4/16/09

- Mr. Cohen mentions that they recently sent a revised recall letter to FDA John Liu (SAN-DO recall coordinator) and Howard Levine (FDA/Office of the Commissioner/ Office of Chief Council) for approval. Since this letter was still being reviewed, we were not able to collect it.
- We inform Mr. Lee Cohen that we would call them (Setton) when we return to close the inspection. Mr. Cohen said he would let the Plant Manager and General Manager of the Terra Bella know of this information. He mentioned a series of corrective actions taken and planned actions of the firm (i.e., (b) (4) items in the remediation presentation, Exhibit #89) which are to be completed in a couple of weeks.
- At the end of the day, it was determined an employee tends to record the incorrect year and/or flips the day and month on the records. This was discussed with the firm's management.

4/20/09

- Setton voluntarily revises its recall notices to include the 2007 year crop packed in 2008 crop year, (Attachment D page 6). The customer recall notice is dated 4/19/09, Attachment J (example of a letter).

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4/27/09

- o Setton International Foods (firm's sister plant) also issues a revised recall notice to include the 2007 year crop packed in 2008 crop year.

4/30/09

- o The FDA 482c (Notice of Inspection-Request for Records) and 414 Attachment are issued to Mr. Lapietra (in the absence of Mr. Setton) upon arrival to the firm and prior to the discussion with management meeting. FDA 463a (Affidavit), FDA 484 (Receipt for Samples) (signed on 4/30/09), FDA 483 (Inspectional Observations) and copies of 21 CFR 110 (Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food) and parts of the FD&C Act (Chapter II-201 Definitions, Chapter III-301 Prohibited Acts & Chapter IV-Foods 401 & 402) were presented and discussed with the firm's management. See the headings below titled, Objectionable Conditions and Management's Response and Discussion with Management (on page 64) of this inspectional report for more information.

INTERSTATE COMMERCE

Raw pistachios were received from State of (b) (4) growers in 2007 and 2008 which accounts for approximately (b) (4) % of the pistachios processed at the firm (See Exhibit #40). The (b) (4) pistachios were mixed in with California grown pistachios. The remainder of the raw pistachios are grown and harvested in California.

The firm's general promotion of their pistachios and other nut products is through direct sales conducted by brokers and their own sales staff located at Setton International Foods, Inc., Commack, NY. The firm's products are promoted also at trade shows and conventions. Distribution of products is throughout the United States which accounts for about (b) (4) % of their annual sales. About (b) (4) % of that (b) (4) % are the firm's products that go out of the State of California. About (b) (4) % of the firm's products go to foreign countries. Exhibit #41 lists the pounds exported for the year 2008 to the various foreign countries. See Exhibit #42 for the firm's customer list.

Private laboratory testing conducted by (b) (4) requested by Setton Pistachio of Terra Bella, Inc., found *Salmonella* in their processed In-Shell Roasted/Salted Pistachios product (b) (4) pounds) which was shipped by the firm on 10/14/08 to Planters (b) (4) under Bill of Lading Order Number (b) (4) w/PO# (b) (4), FMO number 2818C03LgB-3, Exhibit #19 and FACTS sample DOC 501602.

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On 3/12/09, the firm shipped to Kraft Planters, (b) (4) their processed Roasted/Salted Pistachio Kernels (b) (4) pounds) under Bill of Lading Order Number (b) (4) (w/PO# (b) (4)), Invoice number (b) (4) (w/PO# (b) (4)), and FMO number 0578W/M which private laboratory firm requested testing by (b) (4) found positive for *Salmonella* (See Exhibit #23 and FACTS sample DOC 501603).

On 3/18/09, the firm shipped to Costco (b) (4) their processed In-shell Roasted/Salted Pistachios (b) (4) pounds) under Bill of Lading Order Number (b) (4) (w/PO# (b) (4)) FMO number 0588D05XLA-2). A sample of this product was collected and sent by the firm to a private laboratory, (b) (4) for testing and found positive for *Salmonella* after the firm had shipped the product (See Exhibit #78 page 3 and FACTS sample DOC 501608).

About (b) (4) % of (b) (4) lbs a year) of the firm's pistachio kernels are sent to (b) (4) in (b) (4) for manual hand-sorting (example of a random shipment is in Exhibit #44). The hand-sorted kernels are returned to Setton in Terra Bella firm, CA. Mr. Campos said they began sending kernels to (b) (4) to be hand-sorted about (b) (4) years ago. Mr. Gibbons said this is very labor intensive for his personnel to perform so these kernels are sent to (b) (4). Other than these pistachios kernels that are later returned to the (b) (4) (b) (4) receives about (b) (4) lbs. a year of this firm's pistachio products.

JURISDICTION

The products currently marketed are subject to the FD&C Act because raw pistachios from the State of (b) (4) almonds from the State of (b) (4) and by an ingredient used in their roasted garlic/onion flavored pistachio product are received from interstate commerce suppliers. The firm distributes their processed or repacked pistachio and nut products throughout the United States and to foreign countries (See Exhibit #42). The firm's current labels for their pistachio, cashew, almond and macadamia products are in Exhibit #96-97.

Setton Pistachio of Terra Bella, Inc. does provide, upon request from a customer, a Federal Food, Drug & Cosmetic Act Letter of Guarantee. The current one used is dated January 24, 2009 and was signed by General Manager, Nicolo (Nick) (NMI) Lapietra (See Exhibit #45 pages 3 & 4). The letter states "The Pistachio products comprising each shipment made by Setton Pistachio is hereby guaranteed, as of the date of such shipment not adulterated or misbranded within the meaning of Federal Food, Drug and Cosmetic Act with all revisions and amendments pertaining thereto, and all applicable regulations such as

(b) (3) (A)

(b) (3) (A)

" Listed in the letter covered by the FDA

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Guarantee is "3. Roasted and Salted 21/25 Onion and Garlic Flavor." FDA FACTS sample 482179, Roasted/Salted Garlic/Onion Flavored Pistachios in 25 lb. plastic lined cartons, collected on 3/30/2009, was positive for *Salmonella montevideo*.

The following product information is reported by Investigator Hamaoka. The firm processes pistachios (raw, roasted, unsalted, salted, flavored or red colored in-shells and raw, roasted, whole, split or diced kernels) and repacks pistachios and other nuts (almond, macadamia and cashew), Exhibit #46, firm's product list. The firm does not (b) (4) or (b) (4) its pistachios. Mr. Gibbons said the firm processes (b) (4) lbs. of pistachios a year. About (b) (4)% of the firm's products are kernels and about (b) (4)% are in-shell pistachios. About (b) (4)% of the firm's pistachio products are un-roasted and are mostly distributed to export customers. Mr. Gibbons said raw kernels are about (b) (4)% of their pistachio products.

Mr. Aguilera said they do request FD&C guaranty from their spice/flavoring ingredient supplier, Exhibit #47 (example of one).

COA for microbiological analysis, aflatoxins and peroxide values are provided to customers based on customer requests. If the customer does not specify which laboratory to use, the COA's are from either (b) (4) or (b) (4) (b) (4)

Setton Farms and SunSet Valley are the firm's own brands. The firm co-packs for other firms. Some of the brands they co-pack under are (b) (4) (b) (4) (b) (4) and (b) (4) See Exhibit #97 for labels.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

FDA official credentials shown to the following individuals: Joshua J. Setton, President/CEO, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA and Setton International Foods, Inc., Commack, NY; Harris (Lee) L. Cohen, Production Manager (according to sign in sheet done on 3/27/09 or Plant Manager, Setton International Foods, Inc., Commack, NY; Nicolo (NMI) Lapietra, General Manager, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA; Jeffrey J. Gibbons, Plant Manager, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA; Agustin (NMI) Gonzalez, Jr., Production Manager, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA; Frank G. Aguilera, Quality Supervisor, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA; Octavio (Tavi) (NMI) Campos, Production Supervisor, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA; (b) (6) (b) (6) Office Assistant, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA; David (middle initial not provided) Goad, Project Manager, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA; Attorneys (b) (4) and

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the following consultants;^{(b) (4)}

(b) (4)

(b) (4)

(b) (4)

I, Larkin R. Buckalew introduced myself to the following consultants:^{(b) (4)}

(b) (4)

and^{(b) (4)}

(b) (4)

We (one or more FDA Investigators present on the respective dates mentioned on the chart on page 8) dealt with the following individuals during this inspection: Joshua J. Setton, President/CEO, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA and Setton International Foods, Inc., Commack, NY; Harris (Lee) L. Cohen, Production Manager (according to sign in sheet done on 3/27/09) or Plant Manager, Setton International Foods, Inc., Commack, NY; Nicolo (Nick) (NMI) Lapietra, General Manager, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA; Jeffrey (Jeff) J. Gibbons, Plant Manager, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA; Frank G. Aguilera, Quality Supervisor, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA; ^{(b) (6)} Office Assistant, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA; and David Goad, Project Manager, Setton Pistachio of Terra Bella, CA.

Other key Setton Pistachio of Terra Bella, Inc., Terra Bella, CA employees we dealt with were Octavio (Tavi) (NMI) Campos, Production Supervisor; Richeliu (Ricardo) G. Corrales, Shipping Manager; Agustin (NMI) Gonzalez, Jr., Production Manager; Trudy G. Terrel, Hand-sorting Supervisor; Dennis K. Mott, Supervisor; and Alfredo (NMI) Nunes, Electrical Department Supervisor.

The attorneys we (one or more FDA Investigators present on the respective dates mentioned on the chart on page 8) dealt with were^{(b) (4)}

(b) (4)

The consultants we (one or more FDA Investigators present on the respective dates mentioned on the chart on page 8) dealt with were^{(b) (4)}

(b) (4)

All the above individuals provided information used in this report and the information provided by them is captured under the following headings in this report: History, Interstate Commerce, Jurisdiction, Firm's Training Program, Manufacturing/Design Operations,

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Microbiological, Manufacturing Codes, Complaints, Recall Procedures, Objectionable Conditions and Management's Response, Refusals, General Discussion with Management, Samples Collected, Voluntary Corrections, Exhibits Collected, and Attachments.

We (one or more FDA Investigators present on the respective dates mentioned on the chart on page 8) were accompanied during the inspection of the facility by Joshua J. Setton, President/CEO, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA and Setton International Foods, Inc., Commack, NY (1 day); Harris (Lee) L. Cohen, Production Manager (according to sign in sheet done on 3/27/09) or Plant Manager, Setton International Foods, Inc., Commack, NY (3 days); Nicolo (NMI) Lapietra, General Manager, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA (2 days); Jeffrey J. Gibbons, Plant Manager, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA (1 day); Agustin (NMI) Gonzalez, Jr., Production Manager, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA (1 day); Octavio (Tavi) (NMI) Campos, Production Supervisor, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA (1 day); Dennis K. Mott, Supervisor, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA (1 day); Octavio (Tavi) (NMI) Campos, Production Supervisor, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA; (1 day); Frank G. Aguilera, Quality Supervisor, Setton Pistachio of Terra Bella, Inc., Terra Bella, CA (1 day); Trudy G. Terrel, Hand sorting Supervisor, Setton Pistachio of Terra Bella, Inc. (2 days); and consultants^{(b) (4)} and Consulting Group^{(b) (4)} and^{(b) (4)}

Joshua J. Setton, President/CEO is the most responsible individual for overseeing all operations conducted at Setton Pistachio of Terra Bella, Inc. He maintains an office at the sister firm Setton International Foods of Brooklyn, Inc. (referred to by the firm's management as Setton International Foods, Inc., Commack, NY). Mr. Setton was present during this inspection at the Terra Bella, CA site on 3/26, 27, 28, 30, & 31/2009 [See FDA 482's dated 3/26/09, 3/27/2009 & 3/28/2009; FDA 482c's dated 3/30/2009 & 3/31/2009; and FDA inspection sign-in lists dated 3/27/2009 and 3/30/2009 (Exhibit #3 & 4)]. Mr. Setton is Setton Pistachio of Terra Bella, Inc.'s corporate President and he signed Setton Pistachio of Terra Bella, Inc.'s articles of incorporation dated July 21, 1995 (See Exhibit #5). Prior to the issuance of the second FDA 482 (Notice of Inspection) and the FDA 482c (Notice of Inspection-Request for Records) Mr. Setton acknowledged that he was the most responsible person present. On the first day of the inspection, Mr. Setton informed us that he had stopped all domestic distribution, had begun testing all loads going to domestic customers and that they planned to^{(b) (4)} their products.

Nicolo (Nick) (NMI) Lapietra, General Manager, is the most responsible individual, at the Setton Pistachio of Terra Bella, Inc. processing site. He maintains his office at this Terra Bella facility. He reports directly to Joshua J. Setton, President/CEO (See Exhibit #48 page 1). His authority to prevent, detect, and correct violations was demonstrated during the inspection. Mr. Lapietra is the first person who is notified at the firm when an environmental swab or a pistachio product is found to contain a pathogen, for example,

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Salmonella. Certificates of Origin for pistachios are signed by Mr. Lapietra, the Genetically modified Organism Statement for tree nuts is signed by Mr. Lapietra, the Setton Pistachio of Terra Bella, Inc.'s Federal Food, Drug & Cosmetic Act Letter of Guaranty is signed by Mr. Lapietra (See Exhibit #45), and the Setton Pistachio of Terra Bella, Inc.'s recall letter to customers is signed by Mr. Lapietra (See Attachment F, G, I & J). Mr. Lapietra oversees all product shipping and receiving operations. Employees involved in shipping and receiving product report to him (See Exhibit #48, page 3). Mr. Lapietra said he was responsible for the Terra Bella firm and is on-site at the Terra Bella facility on a daily basis more than Mr. Setton or Mr. Cohen who both retain offices at the New York firm. He has been at the Terra Bella facility since it began operations at this location in 1995. Prior to the move he was the Plant Manager and in-charge of Setton Pistachio Company, Inc. in Madera, CA from 1986 to 1995 that was also owned by Mr. Joshua J. Setton. On the first day of the inspection, prior to issuing the FDA 482 (Notice of Inspection), Mr. Gibbons identified Mr. Lapietra as the one in charge of the Terra Bella facility in the absence of Mr. Setton. Mr. Lapietra accepted the FDA 482 (Notice of Inspection), the FDA 482c (Notice of Inspection-Request for Records), the FDA 483 (Inspectional Observations) and on 4/30/09 signed the FDA 484.

Jeffrey (Jeff) J. Gibbons, Plant Manager is the most responsible individual for the day to day operations conducted at Setton Pistachio of Terra Bella, Inc. Mr. Gibbons reports to both General Manager, Nick Lapietra and President/CEO, Joshua J. Setton (See Exhibit #48 pages 1 & 2). Mr. Gibbons stated during the inspection he is responsible for grower receiving and field operations, grower relations, is part of a pistachio commission trade group, does industry reporting, handles grower payments, has some capital budget responsibilities, and handles/investigates customer complaints. Agustin (NMI) Gonzalez, Jr., Production Manager; Frank G. Aguilera, Quality Supervisor; and Octavio (NMI) Campos, Production Supervisor all report to Mr. Gibbons (See Exhibit #48 pages 2, 4, 5 & 6). Mr. Gibbons said he has been with the firm since 1995. See the headings below titled, Complaints and Refusals (on pages 63 and 81), in this inspection report for requests for the firm's complaint file.

Harris (Lee) L. Cohen, Plant Manager of the sister repacking facility Setton International Foods, Inc., Commack, NY, is the son-in-law of Joshua J. Setton, President/CEO and reports directly to him (See Exhibit #48 page 1). In the absence of Mr. Setton, Lee Cohen became his representative and the spokesperson for the Setton Pistachio of Terra Bella, Inc.'s site. Mr. Cohen was the person responsible for handling the pistachio recall. He refused FDA the use of a camera during the inspection and directed the firm's personnel not to sign the FDA 463a Affidavit. He informed us that it was his company's policy to not permit photographs or sign affidavits (See subsection titled, Refusals, on page 81). He informed us he was in charge of the inspection at Setton Pistachio of Terra Bella, Inc. when his father-in-law, Mr. Joshua Setton, was not available.

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The firm is a family owned business. The following corporate officers of Setton Pistachio of Terra Bella, Inc. retain offices at Setton International Foods of Brooklyn, Inc. (dba Setton International Foods, Inc.) Commack, NY, (see Exhibit #48 page 1 and Attachment C):

Joshua J. Setton, President

Morris J. Setton, Vice President (Mr. Joshua Setton's brother)

Stewart "?" Feliner, Chief Financial Officer

"?" denotes that the firm's management did not know of Mr. Feliner's middle initial

The following are other key individuals who provided information for this inspection report which is reported by Investigator Hamaoka.

Octavio (Tavi) (NMI) Campos, Production Supervisor has been working at this location since 1989 when it was owned by Dole who also processed pistachios at this location. He has been with Setton Pistachio of Terra Bella, Inc. since its beginning on 8/15/95. Mr. Campos is in charge of the processing operations of the plant and in charge of assuring that orders are filled. He provided processing, packaging and manufacturing code breakdown information and some processing records during the inspection. He, along with Mr. Gonzalez, Jr., and Mr. Aguilera, would handle process deviations. Initially he informed us (FDB Investigator Truong, FDA Investigator Buckalew and me) that he does not receive any notification of positive *Salmonella* test results. During the interviewing with Mr. Corrales, Shipping Manager, (in the presence of Mr. Campos), Mr. Corrales stated he lets Mr. Campos and Mr. Aguilera know of any positive *Salmonella* test results. Mr. Campos did not respond to Mr. Corrales' statement. Mr. Campos reports to Mr. Gonzalez, Jr. (Plant Supervisor) and Mr. Gibbons.

Frank G. Aguilera, Quality Supervisor said he has been with the firm for seven years. He said he has worked at Paramount Farms and Wm. Bolthouse Farms, Inc. He is in charge of Setton's quality control, HACCP, sanitation, pest control and microbiological tests, logics control, fiber and film ordering and mock recalls. Mr. Aguilera said he currently has about ^{(b) (4)} personnel working for him and during the peak season he can have ^{(b) (4)} personnel working in his department. He, along with Mr. Gonzalez, Jr., and Mr. Campos, would handle process deviations. Initially he informed us (FDB Investigator Truong, FDA Investigator Buckalew and me) that he does not receive any notification of positive *Salmonella* test results. During the interviewing with Mr. Corrales, Shipping Manager, (in the presence of Mr. Aguilera), Mr. Corrales stated he informs Mr. Campos and Mr. Aguilera of any positive *Salmonella* test results. Mr. Aguilera did not correct Mr. Corrales' statement. Mr. Gonzalez provided sanitation, HACCP, quality control, pest control, FMO/lot code information and records of this report. Mr. Aguilera reports to Mr. Gibbons (Plant Supervisor).

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Agustin (NMI) Gonzalez Jr., Plant Supervisor is in charge of production, related production training and the hiring and firing of production employees. He with Mr. Aguilera and Mr. Campos would handle process deviations. Mr. Gonzalez reports to Mr. Gibbons. On 3/27/09, Mr. Gonzalez was summoned by Mr. Cohen to decipher certain production runs and there related missing records.

(b) (6) **Office Clerk** has worked with the firm since 1995 when she was in production. Since 2007 she has worked with shipping, receiving and accounts payable. Ms. (b) (6) provided information and made the copies for most of the requested records of the five positive *Salmonella* samples, GNC, Sanfilippo and Costco complaint trace backs and 4 samples testes by (b) (4) trace backs, requested recall records, microbiological results, bills of lading, invoices, production and quality control records. She was observed taking notes during our meetings with management and kept a log of the copied records provided to us, Exhibit #49. Ms. (b) (6) answered questions regarding the records and provided a spreadsheet time line for the five positive *Salmonella* samples, Exhibit #50. She reports to Anna Waters (Office Manager) who reports to Mr. Lapietra (General Manager).

Richeliu (Ricardo) G. Corrales, Shipping Manager works in the shipping department. One of Mr. Corrales duties is to submit the test samples to the respective laboratories (b) (4) that were collected by the firm's quality control department. Mr. Corrales provided us (FDB Investigator Truong, FDA Investigator Buckalew and me) with information regarding receiving microbiological test results. He said there is 4-5 day turn around time when submitting a sample to the laboratory for *Salmonella* analysis via e-mail. He mentioned they have an agreement with the laboratories to call Mr. Lapietra if there is a suspect positive on any preliminary microbiological test results. He said he receives the microbiological test results from Mr. Lapietra and it goes into their (b) (4) computer e-mail system to notify the shipping department if the product can be shipped out. He said he notifies Mr. Aguilera and Mr. Campos of any positive microbiological test results or high aflatoxin results. Mr. Corrales reports to Mr. Lapietra.

Trudy G. Terrel (Hand-sort Supervisor) accompanied the inspection sampling team during the environmental sampling and was in charge of the Setton's sampling personnel who collected duplicate samples. She provided the names of equipment and processing areas being sampled to the FDA/FDB sampling team. She notified Mr. Cohen when FDA began using the camera. She was the one who went to look for the requested retain/library samples and who informed me that they keep the retain/library samples for (b) (4) months before they are discarded. (The GNC complaint, Sanfilippo complaint and SEA-DO FACTS 73148 complaint were prior to December 2008. As a result, no samples were available related to these complaints. Ms. Terrel reports to Mr. Campos (Production Supervisor).

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Dennis K. Mott, Product Supervisor accompanied us (FDB Investigators Bloxsom & Truong and FDA Investigator Buckalew & me) during the walk through of the red dye line. He also provided us most of the labels submitted in this inspection report (Exhibit #96 & 97). He reports to Mr. Gonzalez, Jr. (Plant Supervisor).

Alfredo (NMI) Nunes, Electrical Department Supervisor was summoned to answer Investigator Buckalew's inquiries of the temperature monitoring devices and their calibrations of the roasters. He reports to Mr. Gibbons (Plant Manager).

During this inspection, the firm's management provided their organization structure for Setton Pistachio of Terra Bella and Setton International Foods, Inc. (Exhibit #48) which were reviewed with them regarding the aforementioned information.

FIRM'S TRAINING PROGRAM

Frank G. Aguilera, Quality Supervisor, stated that employees receive Good Manufacturing Practices (GMP) for foods training when hired and (b) (4) thereafter there is a refresher course. There are (b) (4) meetings where quality, HACCP, and GMP subjects are discussed and presentations are done such as how allergen cross contamination can occur. The firm keeps meeting notes and signature sheets identifying employees who attended the meeting. There are written instructions for employees who are then evaluated on performance and then the employees performance is reviewed to see if additional training is needed.

On 4/16/09 it was found that one of the firm's employees tends to record the incorrect year and/or month on the records. The day and month were reversed on some of that employee's processing records. This was discussed with the firm's management. See heading History, subsection *Timeline of Some of the Events Related to this Inspection*, for date 4/16/09 (on page 13) of this inspection report.

MANUFACTURING/DESIGN OPERATIONS

Incoming field harvested pistachios (outside the processing building):

The following preprocessing pistachio operations to the silo storage step were observed (in dry run) and reported by Investigator Rhyu. The following information was from Mr. Gibbons and Mr. Cohen who accompanied FDB Investigator Bloxsom, FDA Investigator Hamaoka and me on 4/2/09. Diagrams of the firm are in Exhibit #15.

Pistachio trees last hundreds of years. Their harvest is from September to October (usually 6 weeks). Pistachio trees bloom around April 1st to around May 15th, developing its shells

and hulls first. Around July the “meat” starts to form inside the shell. The size of the shell and “meat” depends on the weather conditions and the availability of water.

Process for the Incoming Field-Picked Pistachios

(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



Process for the Pistachios Inside the Processing Building

The following pistachio processing section was reported by Investigator Buckalew.

*During the dry run of this incoming process we were informed by Mr. Gibbons and Mr. Cohen that (b) (4) water is used on this side of the process also. Mr. Aguilera later

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informed us that the firm (b) (4) the (b) (4) water that is used at the silo side of the process (incoming field pistachio process) and that (b) (4) water is used on the processing side (after silo storage) of the plant.

Mr. Aguilera provided Investigator Buckalew and Hamaoka the (b) (4) and (b) (4) water (b) (4) reports and randomly picked (b) (4) water analysis (See Exhibit #51). See the heading below, Microbiological Testing (on page 60), for more information on this inspection report.

On 3/26/2009, at the start of the inspection, there was no product schedule list obtained to identify what products were run on that day. On that day, Mr. Gibbons informed Investigators Hamaoka and Fernandez that they planned to conduct validation studies on (b) (4) roasters. The second day of the inspection, 3/27/2009, the firm was scheduled to do the following operations: in-shell pistachio sizing, color sorting, hand-sorting; kernel hand and color sorting; and kernel roasting (Exhibit #1). The firm's validation study was being conducted on the (b) (4) roaster to verify it was capable of achieving a microbiological kill step for *Salmonella*. Environmental swabs were taken at the (b) (4) roaster but no product was running. Thus, no in-line samples were collected. Between 3/28/2009 and 4/16/2009, we did not observe any packaging operations and the firm's management stated that they had not packaged any products during that time span. On 4/30/2009, the firm was observed packing raw in-shell pistachios into woven bags for export.

For the inspection period, after March 27, 2009 the firm stopped all product packaging and began revamping their operations because of the *Salmonella* problem in their pistachio products. Pistachio and cashew roasting operations were stopped and will resume when the first roaster is validated followed by the other (b) (4) roasters which will not operate until they are also validated. The firm did provide their own flow charts of how the facility operations functioned prior to the shutdown. On March 26, 2009 the firm provided a Pistachio flow chart (Exhibit #52 pages 20-23). Later during the inspection, they provided the following flow charts: Raw Process In-Shell Pistachios, Raw Process Shelled Pistachios, Artificially Raw Open Pistachios, In-shell Roasted Line, Kernel Roasted Line, Roasted Open Line, Roasted Flavored Pistachios, and Cashew Roasted Line) (Exhibit #53) and also provided flow charts showing where raw and roasted pistachios had been run on shared equipment (South Hand-sorting Room, Bulk Line # (b) (4) and the New Building Bin Transfer Hopper) (See Exhibit #54).

The list of products that were manufactured at the facility prior to the current inspection can be found in Exhibit #46. The firm did have in place a HACCP (Hazard Analysis and Critical Control Point) program (Exhibit #52) that management stated on 4/30/2009 would be revised. The CCP (Critical Control Point) in that plan was at (b) (4) (b) (4) to control the hazard of possible (b) (4)

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(b) (4). The firm had a food allergen program guidance document (Exhibit #55) but had two allergens wheat and soy that were not covered in the guidance which management stated on 4/30/2009 was under review by their hired consultants (Exhibit #97 page 4a). The firm did have in place a pest control program (Exhibit #56). Byproducts created by processing the pistachios are being distributed by the firm. They include pistachio shells for (b) (4) picked up and delivered by (b) (4) (Exhibit #57 pages 2-24); (b) (4) sent to (b) (4) (Exhibit #57 pages 25-26); and (b) (4) sent to (b) (4) (Exhibit #57 pages 27-28, Attachment M and DOC 538401).

From the inspection dates on or after March 26, 2009, based on team member walk through and sampling site knowledge, a flow diagram was constructed for the raw and roasted pistachio as they would have existed prior to the start of the inspection. The following flowchart was drafted by Investigator Gee who also utilized Investigator Buckalew's and Hamaoka's input during that process.

InShell Pistachio Flow Chart

(b) (4)



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(b) (4)

All of the rejects from the (b) (4) process which accumulate at the (b) (4)
(b) (4) are processed into (b) (4)

Shelled Pistachio Processing Flow Chart

(b) (4)

The following subsection on pistachio roasting, pistachio product packaging room and equipment was reported by Investigator Hamaoka.

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The firm has (b) (4) roasters: the (b) (4) and the (b) (4) roasters. The (b) (4) roaster is for kernel and in-shell pistachios, since it has a polisher. Mr. Campos said the (b) (4) roaster has been at this facility since the time Dole Nut Division owned the facility. He said Dole Nut Division began operations in 1989. He said the (b) (4) roaster can roast (b) (4) lb. of pistachios an (b) (4)

The (b) (4) roaster was transferred to Setton Pistachio of Terra Bella from Mr. Setton's former firm, Setton Pistachio Company located in Madera, CA. The (b) (4) roasts only kernels. Mr. Aguilera explained that they have placed a (b) (4) in this roaster and it now has (b) (4) in it, like the (b) (4) roaster. It will be able to do in-shell pistachios since the firm has installed a (b) (4) section in it. Mr. Aguilera said it has been down since about August 20, 2008. Kernels do not go through the (b) (4) or (b) (4) step of the roaster. Only the In-shell pistachios use the (b) (4) section of the roaster. When the (b) (4) roaster was operating, it had only (b) (4) in it and it roasted about (b) (4) lb. of pistachio kernels an (b) (4). Mr. Campos explained it had (b) (4) than the (b) (4) roaster. The firm plans to start using the (b) (4) roaster after it is validated.

Mr. Gibbons said they developed the roasting time and temperatures (in the two flow charts listed above in which the temperatures noted are not internal product temperatures but are the roaster's oven temperatures) and these parameters were influenced by their customers' preferences on the final products. He stated he believes the roasting time and temperatures his firm has been using is a sufficient kill step for *Salmonella* microorganism and on 3/26/09 he informed Investigator Hamaoka that they had already scheduled to have the roasters' times and temperatures validated the next day.

Prior to 1/2009, the firm did not maintain any type of verification records for roasting times, temperatures or bed depths. Mr. Cohen said they recorded the roasting parameters on a white board that got erased. According Mr. Aguilera re-roasting is their corrective action for the pistachios that previously tested positive for *Salmonella*. The firm had not conducted any validation studies on their roasters to verify that it was a kill step for *Salmonella*. This year, the firm began maintaining roasting records but these records had no FMO/lots referenced and the time and date for roasting was not noted. Examples of some of these records are in Exhibit #58. The firm has not calibrated any of the roasters' temperature and timing monitoring devices. Their roasters have not been validated. See the subsections below titled, Objectionable Conditions and Management Response, Observation 2 (on page 71) of this inspection report for more information and the attached FDA 483-Inspectional Observations.

FDA Investigator Fernandez observed holes in the roof above the (b) (4) roaster in the roaster room, Exhibit #59 pages 1-3. Also, she noted cloth-like material that was moist wrapped around the braces of the overflow water funnel of the dewatering screen in the roaster room. See the heading below titled, Objectionable Conditions and Management

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Response, Observations 1 and 6 (on page 64 and on page 79) and photographs in Exhibit #59 page 6 of this inspection report.

The pistachio hoppers (for un-roasted pistachios) that feed the roasters are in the same room next to the (b) (4) roasters. The facility was not designed to have a ventilation system to assure there was positive air flow from the areas of the plant that contained roasted products to the areas of the plant that contained raw products. For more information see the subsections below titled, Objectionable Conditions and Management Response, Observations 3 & 4 (on page 73 and 74) of this inspection report.

The following roasting process was described by Mr. Aguilera at the time the inspection team and the firm were collecting environmental samples at the (b) (4) roaster on 3/27/09.

(b) (4)



When the roasters are cleaned, Mr. Campos said the (b) (4) tank is rinsed out with water, then either (b) (4) or (b) (4) is used to sanitize the tank. The little tanks for each roaster are rinsed with water at the end of production.

Below is the product flow in the firm's packaging room and the various sizes of packages each line packs. Un-roasted and roasted pistachios were packaged on Bulk Line (b) (4) located in the packaging room. Roasted products were conveyed from the roaster by conveyor buckets (undedicated when assembled onto the conveyor lines) to the packaging room. Nut products were transported in undedicated bins from the roaster, packaging and the Red Dye Room as shown in the packaging room product flow chart (where bins and bin hoppers are noted). Employees, forklifts, sample carts, brooms and bins crossover from unroasted and roasted areas. Exhibit #85 pages 4 & 5 show the process flow for the in-shell and kernel pistachio products and exhibits how the product flow is not restricted (unroasted and roasted).

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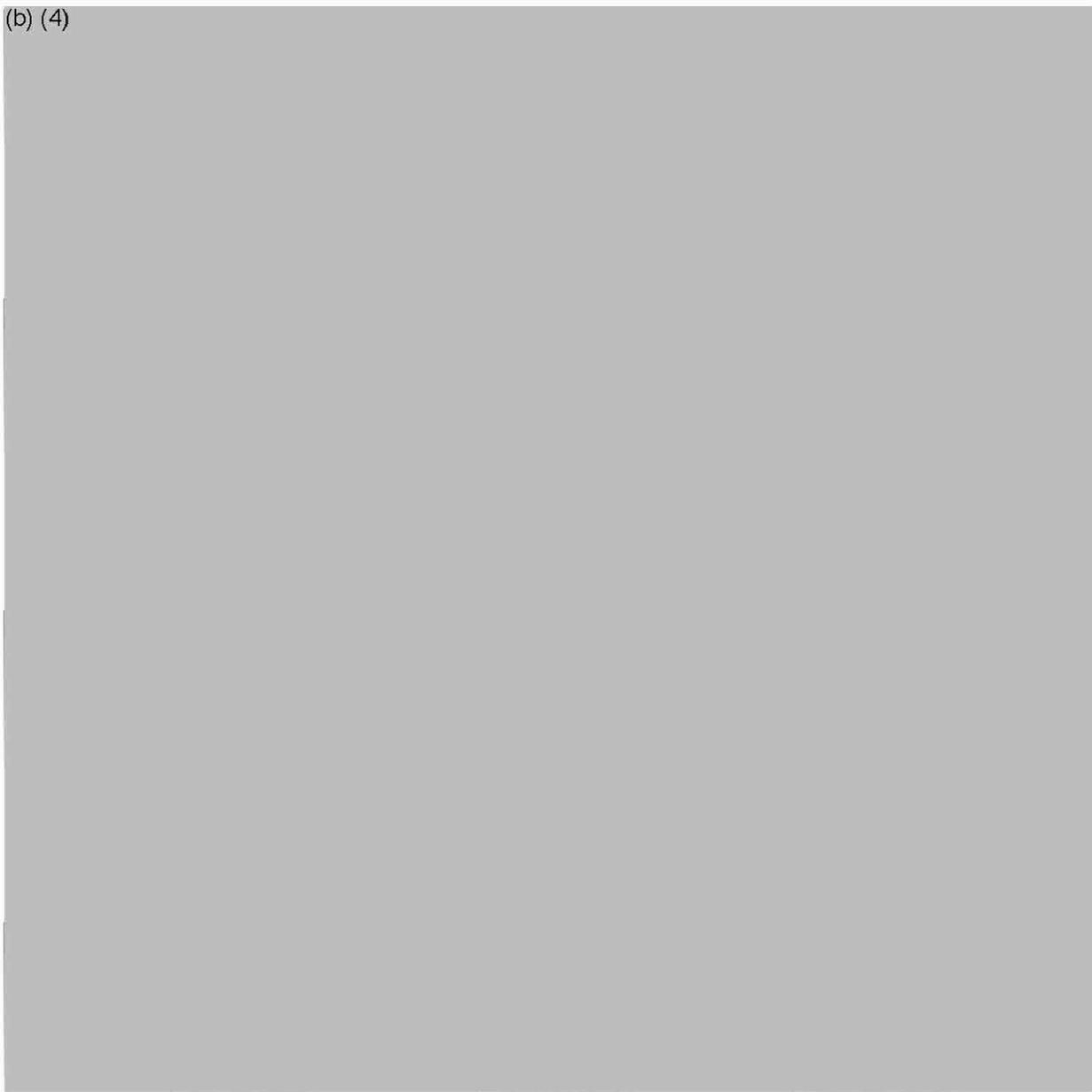
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Besides the Package Room product can also be packed in the South Hand-sort room and the New Building Transfer Hopper. Roasted pistachios that still do not meet the required visual quality can go to the South Hand-sort where un-roasted pistachios are hand-sorted. The New Building Transfer Hopper is used to package un-roasted and roasted products. There was no controlled air flow in the roaster room, packaging room and packaging areas. For more information see the subsections titled, Objectionable Conditions and Management Response, Observations 3 & 4, of this inspection report below (on pages 73 and 74).

(b) (4)



The following paragraph on the cashew roasting was reported by Investigator Buckalew. The firm's cashew oil roaster is located in the (b) (4) area (Exhibit #15 page 1). The roaster, according to management, has not been validated. The cashew roaster's

(b) (4)

The following are estimates on the pounds that New Building Transfer Hopper and South Hand-sort room packaged. This is because each of the 3 times I inquired about these poundage amounts to Mr. Campos they changed.

- o New Building Transfer Hopper packages (b) (4) lbs. (b) (4) poly-bags and (b) (4) lbs totes.
- o The South Hand-sort packages (b) (4) lbs. (b) (4) " or (b) (4)

The following is the process outline on the Red Dye Line as explained by Dennis Mott (Production Supervisor) during the dry run of this production line. (b) (4)

(b) (4)

SANITATION

The following sanitation subsection was reported by Investigator Hamaoka and most of the information was from Mr. Aguilera.

Processing, Packaging and (b) (4)

Mr. Aguilera said his firm does not perform sanitation and cleaning all at once on a certain shift. At the end of production certain types of equipment (i.e., packaging line, roaster, hand-sort, package equipment, related hoppers and conveyor) on a certain schedule are cleaned and sanitized by production personnel. After the firm runs different types of products (i.e., flavors, color dyed, un-salted, roasted and un-roasted) the lines and packaging equipment are manually cleaned. If they run similar products (i.e., roasted, salted with different sizes) the lines and packaging equipment are not cleaned. There were many missing records for the cleaning of packaging equipment. The equipment, lines, floors and walls are manually cleaned. Mr. Campos said after production, the packaging area and equipment are manually brushed, blown with compressed air, manually scrubbed with cleanser, wiped cleaned and sanitized by the packaging personnel. No water is used

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here to clean the packaging equipment. Mr. Aguilera said that they^{(b) (4)} using^{(b) (4)} ppm) and^{(b) (4)} ppm) as a sanitizer. Mr. Aguilera said all of the chemicals and sanitizers are from^{(b) (4)}

According to Mr. Aguilera there is no routine cleaning of equipment and lines upon startup of production since equipment and related lines were already cleaned at the completion of the prior production. Mr. Aguilera said they use an^{(b) (4)} device to check equipment and lines before processing begins. The firm's^{(b) (4)} device is a^{(b) (4)} (Exhibit #62). In interviewing Mr. Aguilera to determine the firm's frequency, identified sites, number of sites, unit's calibration and frequency and verification records of these checks and calibrations were found to be at random. Mr. Aguilera provided some records of the^{(b) (4)} checks (Exhibit #63, but he said that he did not always keep a record of all the^{(b) (4)} checks.. He said he does calibrate the unit but had no calibration records for the positive control checks. Mr. Aguilera said they were implementing new^{(b) (4)} procedures and forms. He provided the information in Exhibit #64 that shows the cleaning of the equipment, the^{(b) (4)} testing and that the^{(b) (4)} results are now used to verify the cleaning of the equipment after each cleaning.

Mr. Aguilera provided the firm's cleaning procedures which were on cleaning records and sanitation schedules. Exhibit #65 shows the cleaning procedures and records prior to 3/30/09. Exhibit #66 shows the cleaning procedures and examples of cleaning records that were to be implemented once they resumed production. When we asked for any formal procedures for cleaning the bins or the silos, he said there were none. He explained the cleaning of the bins and silos to me which is discussed below under the headings of Bins and Silos. He showed us the binder of records called Sanitation Schedule. There were not too many completed ones, so copies of all of these in the binder are in Exhibit #65 pages 1-15. There were many^{(b) (4)} sanitation schedules missing. Initially, Mr. Aguilera said these sanitation schedules are generated^{(b) (4)} for the employees to complete and that the recorded items on the backs of each page are the tasks the employees completed. These were reviewed and signed by the lead person and supervisor. Later, Mr. Aguilera said that all the items listed on his Sanitation Schedule meant they were all performed and the items recorded on the backside of the sheets are the now comments made by the employee performing the tasks.

The firm maintains some sanitation records that had employees' signatures indicating they cleaned the respective piece of equipment. The records also have entries for the lead person and supervisor to sign to indicate they have verified that the equipment was clean. There were so many missing sanitation records that it could not be determined and verified that certain processing and packaging equipment were cleaned prior to running roasted products. Also, most of the packaging equipment cleaning records (Exhibit #65 pages 22-58) did not have entries for the time when they were cleaned and verified. It was not

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possible to determine if the firm actually cleaned and verified the cleaning in between when they processed/packaged raw and roasted products on the same day.

Red Dye Line (aka Flavor Line):

The firm had no records to verify the sanitation and cleaning of the Red Dye line. This line produced the finished product (Garlic/Onion Roasted/Salted Pistachios) that was analyzed by FDA (FACTS #482179, IS is documented on DOC 501601) and that was positive for *Salmonella*. This product was produced on 3/17/09. The Red Dye line is one of the lines where allergen ingredients (wheat and soy) are used, Exhibit #97 page 4a.

Mr. Aguilera said the Red Dye equipment and lines are air blown, swept, water rinsed, scrubbed with a degreaser, water rinsed and sanitized with (b) (4) or (b) (4) Mr. Aguilera said they are in the process of revamping the cleaning and sanitation of the Red Dye line and also the (b) (4). He is working with his chemical supplier, (b) (6) (b) (6) with (b) (4). See more on the firm's Allergen Program below in this Sanitation subsection (on page 44).

Bins:

The firm has no formal procedure for cleaning its bins. Mr. Aguilera said the bins are cleaned (b) (4) or when the bins visually have a build-up of dust/debris. The firm does not have verification or records of when each bin was last cleaned nor does it track which ones were cleaned and when. The firm has about (b) (4) ft bins and (b) (4) ft bins. There are no dedicated bins for roasted and un-roasted product and the bins can be used at any part of the pistachio process. Wooden bins are used for the incoming field-harvested pistachios. The firm does not have adequate controls in place for the sanitation/cleaning of the bins that are used interchangeably for many parts of its process for un-roasted and roasted products. Management (Mr. Aguilera, Mr. Campos, Mr. Gibbons and Mr. Cohen) told us that the bins holding roasted products are lined with a (b) (4) mm gauge plastic bin liner. The bins are washed outside near the (b) (4) Mr. Aguilera said high pressure water is first applied on the bins, then cleanser, manually scrubbed, rinsed and sanitized with (b) (4) at (b) (4) ppm). There are no records prior to 3/26/09 of the checks of the (b) (4) level in the sanitizer for the bins. The firm did not have a way to designate which bins had been used to transport raw product versus roasted product and they had no way to differentiate the bins that had been cleaned and sanitized from those that had not. Since 4/2/09, the firm is currently maintaining sanitation records and (b) (4) level checks for the bin washing. The firm now (b) (4) each bin to indicate what was in the bin before and to assure it is cleaned (b) (4) Mr. Aguilera said he trains this sanitation crew at least (b) (4). The sanitation crew is composed of (b) (4) personnel who work from (b) (4).

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Conveyor Belts and Buckets:

The firm does not maintain any verification or records for cleaning/sanitizing of the conveyor buckets or belts. Mr. Aguilera said the conveyors are removed for cleaning every (b) (4) months. They are cleaned as the bins are cleaned and by the firm's sanitation crew.

After removal, the conveyor buckets are manually washed using a degreaser, rinsed, then dipped in (b) (4) solution and rinsed with fresh water. The firm cleans the conveyors outside. During the inspection, the cleaned conveyor buckets were observed stored outside in an opened storage shed. Some of the cleaned conveyor buckets were not covered by the flexible plastic used to cover them exposing the cleaned conveyor buckets to the open environment. See photograph in Exhibit #59 pages 4-5, Observation #5 of the FDA 483 and the heading Objectionable Conditions and Management Responses, Observation #5 (on page 78). On 4/2/09, the firm's sanitation crew was observed cleaning the conveyor buckets (used to convey food products) outdoors exposed to the outside environment where employee gloves were observed stored on a pipe railing and scrubbing objects were in contact with the ground (below the pipe railing). When the employees returned from their break, they were observed placing the gloves on and picking up the scrubbing objects as they continued to wash the conveyor buckets. See photograph in Exhibit #59, page 8. This was discussed with Mr. Cohen and Mr. Aguilera.

Mr. Aguilera said that after cleaning and when the conveyor buckets are placed back on the conveyor, they are sprayed with one of the sanitizers. Mr. Aguilera said while the conveyor buckets are on the conveyors (in the processing buildings), in between their washings, they are blown free of debris/dust with an air hose and sprayed with either (b) (4)

Silos:

Mr. Aguilera explained two methods for cleaning their silos:

Method One: Before harvest the silos are manually swept and cleaned along with all of the associated equipment (i.e., overhead belts, chutes, conveyors, silo walls, floor, under floor) removing any nuts and debris. Employees enter the silos to manually clean the insides of them. After the manual cleaning (b) (4) ppm) or (b) (4) ppm) is applied to the insides of the silos at high pressure with a (b) (4) hose connected to a portable sprayer and allowed to dry. Initially Mr. Aguilera informed us that he had no silo cleaning records. Later he provided us with Confined Space Entry Permits that each employee signs signifying that they understand the work to be performed and the safety procedures, Exhibit #36. The form indicates to sweep and spray with (b) (4), or (b) (4)

Method Two: After the silos are emptied, they are aired out. Any pistachios on the bottom and top of silos are removed and the insides of the silos are sprayed with (b) (4) or (b) (4)

Finishing Rooms and Sort Tables:

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The finishing rooms and sort tables are wiped (b) (4) with a material cleaning cloth to wipe the dirt.

Sizer and pin pickers:

The sizer and pin pickers are wiped (b) (4)

Hoppers:

The hoppers are air blown, wet cleaned and sanitized by spraying with (b) (4)

The Roasters:

The roasters (b) (4) and (b) (4) are air blown (also the hoppers to the roasters*), and brushed to remove any product, rinsed with water, sprayed with (b) (4) water rinsed and sanitized with (b) (4) ppm) or (b) (4) ppm). *The pistachio hoppers (for un-roasted pistachios) to the roasters were in the same room next to the (b) (4) roasters. There was no controlled air flow in the roaster room. For more information see the subsections titled, Objectionable Conditions and Management Response, Observations 3 & 4 (on pages 73 and 74), of this inspection report below.

After production, the cashew roaster in the New Building is cleaned by draining the oil for (b) (4). The pans and other removable parts were soaked in a degreaser for about (b) (4) manually scrubbed using more degreaser if necessary and sanitized with (b) (4). The floors and production line is rinsed, washed and sanitized with either (b) (4)

Mr. Campos provided maintenance records to the firm's (b) (4) Roaster and (b) (4) Roaster (Exhibit #67). The firm's (b) (4) roaster has been down for maintenance since August 2008.

New Sanitation Procedures:

Later Mr. Aguilera provided the firm's new sanitation procedures dated 3/30/09 for Equipment Cleaning Program, Clean Up Procedures: Packaging Room, Clean Up Procedures: Red Dye Machine, Clean Up Procedures: Roaster, Clean Up Procedures: Sorting Rooms, Clean Up Procedures: Ready-to-eat Room, Drain Cleaning Procedure, Plastic Bin Washing & Sanitizing Procedure and Floor Sweep Procedure, Exhibit #66.

Air hoses:

The end of the air hoses were observed in contact with the floor during the firm's cleanup (when the firm was no longer processing any pistachios). Since a positive *Salmonella* environmental was detected on an air hose by FDA laboratory analysis (FACTS INV 489158, sub 9), I asked the firm's management how they clean and maintain the cleanliness

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of their air hoses. Mr. Aguilera said they do not have any formal written procedures for the air hoses; this air hose was cleaned together with the (b) (4). He provided the cleaning records for the (b) (4) and said this covered the cleaning of this air hose. Mr. Aguilera provided (b) (4) Machine Preventive Maintenance (Exhibit #68) showing the cleaning of the (b) (4) which he said is the document verifying that suspect air hose was being routinely cleaned and sanitized. The record notes (b) (4) machine when Mr. Aguilera referred to it as a (b) (4). The record does not mention the air hose cleaning/sanitizing. The most recent record (Exhibit #68 page 1) shows on 3/30/09 the firm performed the maintenance and calibration of the (b) (4). The FDA environmental, Sub 9 of INV 489158 sample, was collected the next morning on 3/31/09. There was no (b) (4) device reading taken by the firm to verify the cleaning of this hose area.

On 4/14/09, we were informed that the firm had a new air compressor installed in October/November of 2008. The older compressor is now used as a backup. The new compressor's air filter had to be initially changed after the first (b) (4) hours of use. Now it is changed after every (b) (4) hours of use. The older compressor's air filter was changed every (b) (4) hours of use. There is a dial on each compressor that monitors the hours of use. Both air filters use a (b) (4). Information on the air conveying equipment (air compressors) was requested and this information is in Exhibit #69.

Allergen Program:

The firm has a formal allergen procedure, Exhibit #55. It was provided by Mr. Aguilera. The firm identifies pistachios, almonds and cashews as allergen in their processing facility and these are to be segregated. The firm has two products that contain either soy or wheat which are not identified as allergens in the firm's formal allergen program and HACCP plan, (Exhibit #52). FDB Investigator Truong discussed this with Mr. Aguilera. The two products are Asian Soy flavored (soy and wheat) pistachios and Jalapeno flavored (hydrolyzed soy protein) pistachios, Exhibit #97 pages 4a & 7. The soy and wheat are listed in the corresponding products' ingredient statements. Records show that the last time the firm ran an allergen containing product on the Red Dye line was on 11/17/08; Asian Soy pistachios containing soy and wheat was manufactured.

The firm's allergen procedure mentions lot tracking, documentation, separation of lines for the firm's identified allergens (pistachios, almonds and cashews), traffic patterns, regular audits of labels for allergens, Master Cleaning Schedule program, that cleaning logs and records are regularly inspected and stored in binders. The firm does not perform any type of allergen testing. The inspection found that the firm does not ensure that non-allergen containing products are free from allergens at the Red Dye room and the (b) (4) packaging (where (b) (4) other packaging lines are located). See attached FDA 483, Observation #4 and the sections below titled, Objectionable Conditions and Management Response (on page 74), for more information.

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Pest Control:

The firm conducts its own pest control, Exhibit #56 pages 1-2. Rodent traps are checked (b) (4) at various sites of the firm. Bait stations are monitored (b) (4). Glue boards and vector lights are checked and replaced (if needed) (b) (4). The firm maintains records of these checks, Exhibit #56 pages 3-8.

The firm did not perform any type of steam cleaning or verify adequate cleaning after being notified 5 different times of positive *Salmonella* sample results. On 4/14/09 we noticed that firm personnel were performing major manual cleaning of its processing facility; lines and equipment were observed being taken apart, cleaned and replaced, walls were removed and walls built. Especially the roaster room had major repairs, removals, remodeling and additions (i.e. (b) (4) improvements). See the subsection below titled, "General Discussion with Management" of this inspectional report for more information (on page 82).

MICROBIOLOGICAL

The following microbiological section was reported by Investigator Hamaoka. Most of the processing information was from Mr. Campos. Ms (b) (6) furnished most of the copies of the records for the exhibits mentioned in the Microbiological section of this inspection report. Mr. Aguilera provided the microbiological information.

On the first day of the inspection (with FDA Investigator Fernandez and FDB Investigator Truong), Mr. Gibbons said they submit (b) (4) *Salmonella* subs for every (b) (4) lbs. of finished product to be analyzed by (b) (4) for *Salmonella*. The firm's own personnel pull these microbiological samples. He said (b) (4) gram subs are collected, composited and split into (b) (4) g subs to be tested for *Salmonella*. Also, he informed us that prior to Oct 2008, they were submitting (b) (4) subs (b) (4) for *Salmonella* analysis. It was later found that their customer (b) (4) requested the increase in sample subs from (b) (4) in October 2008 and gave the firm no reason for their requested increase. The firm's recently hired consulting microbiologist, (b) (4) (b) (4), informed us on 3/31/09 that he found that the firm had cross contaminated the product samples during their collection. He reported that the same sampling cart, tray tables and scissors were used for un-roasted and roasted pistachio microbiological sample gathering and preparation. Exhibit #70 is the description of the firm's sampling procedures that he compiled.

Mr. Aguilera said they do not test the incoming spices (i.e., chili, lemon, habanero, salt, hickory, garlic/onion) and red dye ingredients (b) (4) microbiologically and that they depend primarily on their spice ingredient suppliers' guarantee. An example of one is in Exhibit #47.

Mr. Aguilera informed me that they perform (b) (4) environmental samples on food contact surfaces (including personnel hands) and non-food contact surfaces for *Salmonella*, *E. coli* and plate count which are analyzed by the (b) (4). He said both (b) (4) personnel and his firm's personnel have collected these environmental samples using (b) (4). We observed the firm using (b) (4) during FDA's sample collection. This was observed since the firm collected duplicate environmental sub-samples with FDA. Mr. Gibbons and Mr. Cohen initially said they performed environmental sampling every (b) (4). Later, Mr. Cohen informed me that they had not performed these environmental samples exactly each (b) (4) but had performed environmental sampling. When we reviewed the records, it showed the firm had not been performing these environmental samples each (b) (4) and did not perform any environmental samples in 2007. I pointed this out to Mr. Aguilera and requested he contact his laboratories for any more information on environmental samples. He said he would and he later informed me they must not have performed any environmental sampling in 2007. The firm has no formal written procedure that defines the firm's established frequency of environmental sampling. The environmental sampling was performed at more random intervals than (b) (4). In review of the (b) (4) environmental records provided by the firm, the following was observed prior to (b) (4) and FDA 3/2009 visits:

Dates	E. Coli	Salmonella	Coliform	APC	Report Dates
12/27/2004	(b) (4)	(b) (4)	(b) (4)	(b) (4)	
4/26/2005	(b) (4)	(b) (4)	(b) (4)	(b) (4)	
8/1/2005					
8/4/2005					
1/24/2006					1/24/2006
1/26/2009					
12/6/2006					
12/8/2006					
2/19/2008					2/22-24/08
10/22/2008					10/24/2008
10/23/2008					10/27/2008
10/27/2008					10/28/2009
1/22/2009					1/23/2008
1/27/2009					1/28/2009
3/16/2009					3/17/2009
3/19/2009					3/24/2009
TOTAL					

The headings at the top of the table are the test descriptions.

The numbers in the test columns of the table indicate the number of environmental samples collected.

For the 10/08 to 3/09 results, see Exhibit # 24, 25, 27, 30, 31 & 32. For prior to 10/08 see Exhibit #43 & 75.

APC is Aerobic Plate Count in which their limit, according to Mr. Aguilera, is (b) (4) cfu/ml. (b) (4) were observed above this tolerance.

Three non-commodity samples (not included in the above table) were collected and submitted by the firm that were negative for *Salmonella*. These were reported on 11/12&17/08, Exhibit #29.

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Mr. Corrales stated that the microbiological results are forwarded to Mr. Lapietra (General Manager), who is also in-charge of the finished product shipping set-up. When there is a suspect positive, the firm has an agreement with the testing laboratories to call Mr. Lapietra or Mr. Corrales (Shipping Manager). Any confirmed positive results (which take about 4-5 days after the submission of a sample) would be e-mailed to Mr. Lapietra, Mr. Corrales and (b) (4) a general e-mail for all office shipping/receiving personnel). When I asked Mr. Aguilera (QC Supervisor) and Mr. Campos (Production Supervisor) if they receive the positive results, they both informed us they do not receive the positive results. I asked to speak to Mr. Corrales, we (FDB Investigator Truong, FDA Investigator Buckalew and I) were informed that he and Mr. Lapietra receive the microbiological results and he does inform Mr. Aguilera and Mr. Campos of any positives.

The firm has been producing pistachios for (b) (4) since (b) (4) (b) (4) requires the firm to provide *Salmonella* test results performed by (b) (4) of each shipment to their related (b) (4). Setton has been routinely collecting and submitting these samples to (b) (4). The pistachios going to (b) (4) represent about (b) (4)% of Setton's business. According to management, they processed (b) (4) shipments in September for (b) (4) shipments in October (b) (4) shipments in November (b) (4) shipments in December (b) (4) shipments in January and (b) (4) shipments in February. Each shipment was about (b) (4) lbs.

In October of 2008, (b) (4) requested that the firm increase its sampling by providing (b) (4) with (b) (4) subs per sample instead of (b) (4) subs in a sample. The firm's management said (b) (4) gave them no reason for this increase. The firm was formerly submitting (b) (4) *Salmonella* subs per sample for every (b) (4) lbs. The firm's employees were formerly pulling (b) (4) (b) (4) gram) sample subs to be tested by (b) (4). In October 2008, (b) (4) increased the subs to be submitted to the (b) (4) subs (b) (4) each) instead of (b) (4). The firm has (b) (4) other customers who request laboratory analyses for *Salmonella* per shipment. These are listed in Exhibit #71. Setton has the choice of laboratories to use for these (b) (4) other customers. The firm uses either (b) (4) laboratories. (b) (4) is located in (b) (4). (b) (4) Thus, the firm's other customers besides (b) (4) and the (b) (4) listed on Exhibit #71, do not require microbiological testing of the pistachios sold them (all of Setton customers are listed on Exhibit #42). There were about (b) (4) times more (b) (4) analyses performed for (b) (4) than the (b) (4) *Salmonella* analyses performed for the firm's other (b) (4) customers. The table below shows the comparison and shows about (b) (4) times more *Salmonella* testing done for pistachios destined to (b) (4).

ESTIMATED SALMONELLA ANALYSIS BY PRIVATE LABORATORIES				
Year	(b) (4)	Crop Year	(b) (4)	(b) (4)
2006	(b) (4)			
2007	(b) (4)			
2008 to 3/2009	163	9/08-3/09	11	12
ESTIMATED TOTALS	333		26	14

The number of samples being reported here is based on available laboratory reports from the laboratories performing the analyses as provided by Setton's management. It is possible that there were unavailable emails/records that were not reviewed by the inspection team.

The firm receives the *Salmonella* test results and provides a copy of the results to the customer requesting the testing. The firm is not aware of any of its customers performing their own *Salmonella* testing. They have not received any customer information feed back on microbiological results from their customers other than (b) (4).

There were no *Salmonella* positives found in the review of (b) (4) records for September 2006 to March 2009. In review of the (b) (4) laboratory records for September 2006 to March 2009, there was one positive *Salmonella* result found and it was for a retest that was performed for Setton on a Kraft product that had previously tested positive for *Salmonella*. This Kraft product was one of the 5 positives discussed below (on page 49) in the subsection below, The Five Positive Salmonella Results that Setton Received.

In review of the (b) (4) microbiological *Salmonella* records provided from September 2006 to March 2009, there were 5 positives found. All of the involved lots going to Kraft Foods related facilities. The five positives all involved the pistachios for the 2008 crop year. The first Kraft positive that Setton received and had knowledge about was in October 2008 on a lot from their 2008 crop of pistachios. There was one positive *Salmonella* test (also involving a Kraft lot) in February 2007, but it indicted it was a dead DNA, Exhibit #72. During the inspection, I forwarded a copy of this exhibit to Dr. Donald Zink at FDA/CFSAN and received no comments. These 6 aforementioned positives were acknowledged by Jeffery J. Gibbons when I had asked him about them on the first day of this inspection, in the presence of FDB Investigator Truong and FDA Investigator Fernandez.

(b) (4) *Salmonella* testing procedures are Enzyme-linked Fluorescent Immunoassay (ELFA), (Association of Official Analytical Chemists) AOAC – R1100201 and (Polymerase Chain Reaction) PCR methods (Attachment N) and (b) (4) procedure is AOAC method 2001.09 (Exhibit #73).

THE FIVE POSITIVE SALMONELLA RESULTS THAT SETTON RECEIVED

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The spreadsheet in Attachment O lists the five FMO/Lots that were destined for or went to a Kraft related facility. These five were confirmed *Salmonella* positives and the results were revealed to the firm by (b) (4). There many missing records for these five FMO/lots and many discrepancies that affidavits attached to DOC 501602 tried to capture. The spreadsheet lists the FMO/Lot, Product, Packing Line, Production Date, Amount Produced, Production Record available to verify (some production records were missing which are noted), Testing Laboratory, Test Date, Test Results, Release #, COA Date, Lab ID, Invoice, Amount of Product sold & shipped, Bill of Lading, Ship Date, Shipped to, Carrier, Product Return Date, Action Taken by the Firm, Re-Roast Date, Re-Test Date, Re-Test COA, Disposition of Product, Links and the related FACTS Sample #s Establishing Interstate Jurisdiction for these five involved FMO/Lots:

- 1) 2818/C03 LgB-2, Exhibit #19
- 2) 3478B14 LgB-2R, Exhibit #20
- 3) 0418W/M, Exhibit #21
- 4) 0548B06 Lg-1, Exhibit #22
- 5) 0578 W/M, Exhibit #23

These five were all roasted salted pistachios. Two were whole pistachio kernels and three were in-shell pistachios. Three were packaged at the New Building Transfer Hopper and two FMO/lots were packaged at the South Sort room. Both the New Building Transfer Hopper and South Sort room were initially identified by the firm as two of their three shared equipment sited to justify the limited scope of their initial voluntary recall. The firm has two of the FMO/lots at their facility on hold. The other three FMO/lots were shipped out. 1) One FMO/lot is on hold at Kraft. 2) Another one was returned by Kraft, blended into other products and sold to domestic customers that the firm (Setton) could not identify. Mr. Aguilera, Mr. Campos and Mr. Cohen said they re-roasted and retested, yet this could not be adequately verified. 3) The third FMO/lot was re-roasted, repacked and shipped to a firm in China. The isolates (1 from (b) (4), 3 from (b) (4) and 1 from (b) (4) (b) (4) to these 5 positive *Salmonella* samples were forward to FDA's laboratory.

Documentary samples were collected for two of the lots that shipped to Kraft related facilities and for two lots documenting a shipment of (b) (4) field-picked pistachios to Setton. See the heading titled, Samples Collected, below (on page 87), DOC 501602, 501603 & 539400.

For the first two positive samples (10/21/09 & 1/8/09), Mr. Aguilera said the firm used re-roasting as a corrective action for these two FMO/Lots that tested positive for *Salmonella*, yet they had not validated their roasters, not calibrated the roaster monitoring devices and roasting records were lacking. They did not begin maintaining roasting records until January 2009. A review of the roasting records (January and later) revealed that Setton did not record the FMO/Lots processed through the roaster. See attached FDA 483, Observation #2 and the heading Objectionable Conditions and Management Response and Discussion with Management, of this inspection report on page 71.

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The following is the information gathered for each of these 5 FMO/lots:

1) FMO/Lot 2818C03 LgB-2 (DOC 501602) - Lab ID (b) (4) (isolate link) (b) (4) # (b) (4)

The isolate that was obtained by (b) (4) (Lab ID (b) (4)) from Setton's pistachios had already been discarded by (b) (4) due to the length of time that lapsed since receiving the sample in October 2008. At the beginning of this inspection, the firm's upper management (Mr. Setton and Mr. Cohen) gave permission to (b) (4) to provide isolates of the positive samples to US FDA. The isolate at (b) (4) derived from a retest of this lot by (b) (4) was forwarded to US FDA Laboratory in Arkansas.

1st version (as explained by Mr. Cohen) : Positive (b) (4) → Positive (b) (4) → Reroast → Blended → Distributed

2nd version (as explained by Mr. Aguilera): Positive (b) (4) → Positive (b) (4) → Re-roast → Negative (b) (4) → Blended → Distributed

(These 2 versions are explained more on page 52 where ** is noted)

These were in-shell roasted salted pistachios packed in (b) (4) lb totes for a Kraft related firm. Ms. (b) (6) said this FMO/Lot was recorded incorrectly on the Bill of Lading (Exhibit #19 page 7). The "LgB-3" should be "LgB-2". There is no invoice for this bill of lading because it was not invoiced since the FMO/Lot tested positive for *Salmonella* and it was returned from the related Kraft firm (b) (4) to Setton. Setton never billed the related Kraft firm. Ms. (b) (6) provided a pick sheet in lieu of an invoice, Exhibit #19 page 6.

For the production, Ms. (b) (6) provided the 10/8/08 FMO tracking log for this FMO/Lot, (Exhibit #19 page 1). Ms. (b) (6) could not locate the Packaging Line sheet for this FMO/lot so she provided the 10/7 & 8/08 Quality Inspection Sheets for FMO# 2818 C03 LgB-2, Exhibit #19 pages 2 & 3, as verification that this FMO/Lot was packaged on 10/7/09. The FMO tracking log and Quality Inspection Sheets show Setton ran Planter's roasted/salted 21/25 pistachios (FMO# 2818C03LgB-2) packaged into (b) (4) lb totes. When I inquired about the "21/25" recording, Ms. (b) (6) told me that the New Building Transfer Hopper record incorrectly lists 21/25 which should be in-shell roasted/salted 26/30 pistachios not 21/25 packaged.

It was noted that the firm packaged un-roasted pistachios before the in-shell roasted salted pistachio product for Kraft. The Quality Inspection Sheet (Exhibit #19 page 22) shows on 10/2/08 Setton ran raw 18/20 US#1 FMO 2748C13XLA-1 prior to the aforementioned (w/FMO# 2818 C03 LgB-2) roasted pistachios at the New Building Transfer Hopper. See attached FDA 483, Observation #4, citing that on 10/2/08 Setton processed and packaged

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on the same packaging equipment raw pistachios (18/20's with FMO# 2748C13XLA-1) before the aforementioned roasted pistachios. The last verified cleaning of this packaging equipment was on 2/16/08 (February 16, 2008) (See attached FDA 483, Observation #4 and subsection below titled, Objectionable Conditions and Management Response, Observation 4, of this inspection report (on page 74).

The Sample Analysis Request Form shows Setton submitted pistachio sample with PO # (b) (4) (relates to FMO/Lot 2818C03 LgB-2) to (b) (4) on 10/9/08, Exhibit #19 page 5. The Certificate of Analysis (COA) for pistachio sample with (b) (4) and release (b) (4) shows the pistachio sample was received by (b) (4) on 10/13/08, Exhibit #19 page 8.

The Bill of Lading with order (b) (4) (isolate link) and PO# (b) (4) for FMO# 2818 C03 LgB-3 shows roasted/salted 26/30 pistachios (b) (4) # & (b) (4) lb. totes) were shipped on 10/14/08 from Terra Bella, CA to Planters (b) (4) (b) (4) Exhibit #19 page 7. Setton packed pistachios with FMO/Lot 2818C03 LgB-2 that were shipped on a waiver on 10/14/08 to Planters (b) (4) Mr. Cohen said Kraft requested for this FMO/Lot of pistachios be sent on a waiver. When the product is shipped on a waiver, it is shipped out before the microbiological analysis is received.

On or about 10/21/08, Setton received the pistachio sample results from (b) (4) relating to this shipment (FMO# 2818 C03 LgB-2) and it was positive for *Salmonella*. This is shown on the (b) (4) COA for pistachio sample with PO# (b) (4) and release (b) (4) (isolate link) received by (b) (4) on 10/13/08, Exhibit #19 page 9.

Mr. Aguilera said they had left-over pistachio product (Exhibit #19 pages 14-17) from this *Salmonella* positive lot of pistachios (FMO# 2818 C03 LgB-2) and after receiving the positive *Salmonella* result from (b) (4) they submitted these left-over pistachios to (b) (4) to (b) (4) analyze. (b) (4) sample date for the *Salmonella* testing was on or about 10/22/08. The (b) (4) Analytical Report with reference # (b) (4) sample date of 10/22/08 and report date of 10/27/08, shows the *Salmonella* was also detected, Exhibit #19 page 15. In review of this record, it is noted that there is no direct link for this sample to the finished product. I showed Mr. Aguilera, Mr. Campos and Ms. (b) (6) without their later handwritten explanations, that the sample submitted to (b) (4) has no direct link to the finished product (Exhibit #19 pages 11&18).

On 10/28/08, the suspect FMO/lot was returned to the firm by Kraft/Planters, Exhibit #19 page 12. The Incoming Product Inspection Log dated 10/28 at 3:15 (Exhibit #19 page 12) shows the return of (b) (4) totes (on pallets - (b) (4) lbs and (b) (4) lbs) of Setton Farms Pistachios. Setton placed the returned pistachios on hold.

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**Setton's management, H. Lee Cohen, initially on 3/27/09 informed the FDB Supervisor Yee and Investigator Buckalew that they re-roasted the returned pistachios, blended them with other pistachios and sold/shipped the blended pistachios to various customers. On 4/8/09 Mr. Aguilera informed us (FDB Investigator Bloxson, FDA Investigator Buckalew and me) that the returned product was retested after roasting. Mr. Aguilera said the returned pistachios were re-roasted, RETESTED, blended and distributed. The affidavit provided by Mr. Campos entitled, Declaration of Confirmation of Re-Roast for 26/30 Lot, does not specify the lot number of pistachios that he states was re-roasted and does not mention retesting of the pistachios, Exhibit 19, page 13.

The copy of the (b) (4) Analytical Report reference (b) (4) with sample date 11/14/08 provided by Mr. Aguilera does not contain any Setton lot numbers. The only reference to Setton lot numbers is a handwritten statement added to the top of the printed report which appears to have been added by someone at Setton Pistachio as no other copies of (b) (4) analytical reports contain such handwritten notes on the top of the printed form.

Mr. Aguilera provided (b) (4) Analytical Report with reference # (b) (4) sample date 11/4/08 and report date 11/6/08 showing negative *Salmonella* results, Exhibit #19 page 18 in which he wrote, "Re ROAST OF Returned Load + Left over Inv 2818 C03 LgB-2 26/30 R/S Return". He also provided the Laboratory Analysis record with collection report # (b) (4) Exhibit #19 page 20. The reference # (b) (4) was not on the list of (b) (4) laboratory sample results that was provided earlier, Exhibit #75. The firm's original Laboratory Analysis record with collection report # (b) (4) did not have the written notation on it (Exhibit #19 page 11) to indicate 26/30 or which lot it was linked to. Also, the notations on Exhibit #19 page 17 that Mr. Aguilera provided appeared to be darker when photocopied and it is not known if they were on the original documents submitted to (b) (4)

The firm's management (Mr. Cohen, Mr. Aguilera and Mr. Campos) was unable to tell us when the product was re-roasted, what the blended pistachio products were and who received the returned, re-roasted, retested pistachios. Setton did not maintain roasting and re-roasting records prior to 1/1/09. Since the product was not going to be returned to the firm's Kraft/Planters customer, Setton management says they retested after re-roasting using the (b) (4) instead of (b) (4). Records provided by the firm showed (b) (4) environmental and (b) (4) pistachio samples (b) (4) was raw pistachios) were analyzed for *Salmonella* by the (b) (4) in October and November 2008 (Exhibit #24, 25, 26, 27 & 28). The only positive detected was the finished product for the aforementioned FMO/lot when retested for the confirmed positive that (b) (4) detected. In October (b) (4) increased its sampling per lot. Mr. Gibbons stated they were not given any reason from (b) (4) for this increase.

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It is not known if Kraft was aware of this positive *Salmonella* result for FMO/Lot 2818C03 LgB-2 and if the other Kraft related facilities had detected *Salmonella* in pistachios received from Setton. The PowerPoint presentation (Attachment A) is silent regarding whether Kraft had knowledge this FMO/Lot tested positive and silent regarding other Kraft facilities receiving Setton pistachios.

Mr. Aguilera said the corrective actions for this FMO/Lot were completed by having the product returned, placed on hold, re-roasted and retested. He said they also had environmental samples collected. After the firm received the initial positive for the FMO/Lot 2818C03 LgB-2 pistachios, records show about (b) (4) environmental samples were analyzed by (b) (4) for *Salmonella* which were all negative, (Exhibit #24 & 25 with dates 10/24 & 27/08). After the firm received the second positive for the same FMO/Lot of pistachios, records show about (b) (4) environmental samples were analyzed by (b) (4) for *Salmonella* which were all negative, (Exhibit #27 with date 10/28/08). From about 10/30/08 to 11/17/08, records show five samples of roasted pistachios are analyzed for *Salmonella* by (b) (4) with negative results, Exhibit #28. The firm did not change its sanitation and sampling frequencies for finished product and environmental samples to more closely monitor the wholesomeness of its finished products.

2) FMO/Lot 3478B14 LgB-2R (R rerun) - Lab ID (b) (4) isolate link)

Positive → 2nd sample Negative (same laboratory) → Re-roasted → Repacked → Exported

These were roasted/salted in-shell pistachios packed in (b) (4) lb (b) (4). The 12/15/08 dated hand-sort record shows 4-Export for 3478B14 LgB1R and that (b) (4) bins of 3478B14 LgB2R were produced, Exhibit #20 page 1. Ms. (b) (6) provided the Quality Inspection Sheet dated 12/19/08 showing an unknown FMO/Lot packed in the New Building Transfer Hopper. When I asked her how she determined this was the correct record for this FMO/Lot, she informed me that it has Planters recorded on it. Ms. (b) (6) provided a Planters roasting log which had no FMO/Lot linking, it is dated 2/27/09 (after the shipment of this product) and has Planters recorded on it, Exhibit #20 page 9.

On or about 1/8/09 the firm received a positive *Salmonella* result linked to roasted in-shell pistachios with FMO #3478B14 LgB-2R, Release (b) (4) and PO# (b) (4) (Exhibit #20 page 3). Setton retested the FMO/Lot, and then received a negative result as noted on (b) (4) COA dated 1/12/09 for Release # (b) (4) and PO# (b) (4) (Exhibit #20 page 5). Ms. (b) (6) said that even though this COA indicates "shipped 1/14/09" and the related bill of lading indicates this FMO# 3478B14 LgB-2R was shipped to Planters (b) (4) (b) (4) these pistachios were not shipped to Planters (Exhibit #20 pages 5 & 8). Exhibit #20 page 3 appears to have a notation (near upper right corner) that may have been covered when this copy was made. The Quality Certificate dated 1/12/09 for Planters (b) (4)

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1b tote bags references the correct (b) (4) release & PO, but per Ms (b) (6) the FMO # was changed to 3518 B 14 LgB-4 since it went to (b) (4) and not to a related Kraft facility.

Setton re-roasted the pistachios. Ms (b) (6) provided the roasting log dated 2/6/09 for the re-roasting (Exhibit #20 page 9) and a Certification of Pistachio Inspection dated 2/9/09 for the pistachios in the (b) (4) boxes (Exhibit #20 page 10). Mr. Cohen said this product was re-roasted and shipped to Hong Kong. The product was not retested. Mr. Campos said the exported pistachios are only tested for aflatoxin if a Certificate of Analysis is requested by the customer. The product is packaged on 2/11-12/09 on Line (b) (4) production records, Exhibit #20 pages 14-19). On 4/9/09, Ms. (b) (6) said this FMO/Lot was packed on 2/11/09. On or about 2/13/09, the pistachios were sold and shipped to a firm in Hong Kong, Exhibit #20 page 22.

The bill of lading dated 2/13/09 shows the shipment to Hong Kong, China and the invoice dated 2/16/09 covers the sale to (b) (4) (it does not reference the PO # to link, the container# is noted, Exhibit 20 pages 22 & 23). The sanitation records for Line (b) (4) for this time frame were not available. There were gaps noted in the sanitation records for Line (b) (4). Also, there were gaps noted in the general sanitation records for this time frame for the cleaning of the roasters and the lines (11/24/08 week to 2/23/09 week, Exhibit #20 page 30 & Exhibit 65).

On 4/8/09, Mr. Campos informed us that the (b) (4) at the end of this lot indicated (b) (4) (b) (4) for this FMO/Lot as it likely had initial had out-of-tolerance aflatoxin levels and it was (b) (4)

After the firm received the third finished product positive, records show about (b) (4) environmental samples were analyzed by (b) (4) for *Salmonella* all of which were negative, (Exhibit #30-31 with dates 1/23 & 28/09). Records did not show any finished pistachios were analyzed for *Salmonella* by (b) (4). There were other finished pistachios analyzed in December 2008 that were going to a (b) (4) related facility that were negative. Setton continued to produce and ship its pistachio products with no changes in its sanitation and microbiological quality control procedures.

3) FMO 0418W/M (b) (4) (Kernels) in (b) (4) (DOC 538400) - Lab ID (b) (4)
(isolate link)

Positive → 2nd sample Negative (same laboratory) → Hold

This FMO/Lot was roasted/salted whole pistachio kernels packed in (b) (4). After receiving the 2/12/09 positive *Salmonella* result for roasted kernels with FMO# 0418W/M (Exhibit #21 pages 5, 6 & 8), the firm submitted another sample on or about 3/10/09 and it tested negative by the same laboratory. Mr. Gibbons informed me that his firm had initially thought that the (b) (4) laboratory had a contamination problem so they sent

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another sample to the (b) (4) laboratory and later started sending their samples to other laboratories. Setton currently has the product on hold at its firm. Mr. Aguilera said their corrective action was to hold this lot and later to re-roast and retest it. The following copies of records were collected from Ms (b) (6)

- o 1/26/09 Roasting Log for Kraft Kernels L/S 21/25 S/F 4 blend, Exhibit #21 page 1.
- o 2/2-3/09 Hand-sort record indicating 4-Planters packed in (after roasting) (b) (4) (Mr. Campos said these were packed at South Hand-sort), Exhibit #21 pages 2-4.
- o 2/12/09 (b) (4) COA indicating positive *Salmonella*, Exhibit #21 page 5.
- o 2/24/09 (b) (4) COA of *Salmonella* specie, Exhibit #21 page 6.
- o 3/16/09 (b) (4) COA of the retest of the same FMO/Lot that was negative for *Salmonella*, Exhibit #21 page 8.
- o 3/24/09 Setton Hold Tag stating hold pending FDA investigation, Exhibit #21 page 9 (EI started 3/26/09).
- o One 4/9/09 Ms (b) (6) says there are no Quality Inspection Sheet and no FMO Tracking Log for this FMO/Lot, Exhibit #21.

There were no (b) (4) microbiological records showing the firm submitted any environmental samples or finished product samples for testing after the notification of this fourth positive on their finished product. The required *Salmonella* analysis for the (b) (4) other February shipments to Kraft related facilities were negative. The firm continued to process and distribute its pistachio products. With this 4th confirmed positive for *Salmonella*, the firm did not change its sanitation (as the new sanitation procedure is dated 3/30/09, Exhibit #66) and sampling frequencies for finished products and/or environmental samples to more closely monitor the wholesomeness of its finished products. Mr. Aguilera provided his new sanitation procedures (Exhibit #66) to us. See also subtitle, New Sanitation Procedures, page 43 of this report. During the inspection, he said he was still working with the microbiologist consultant to develop a sampling program for finished products and environmental sampling.

4) FMO 0548B06 Lg-1 21/25 (DOC 538400) - Lab ID (b) (4) (isolate link)

(b) (4) HOLD
 3 samples → 2 (b) (4) → positive, negative → for re-roasting & re-sampling
 1 (b) (4) → negative

There were no records to verify the type of bulk container used to pack these roasted/salted in-shell pistachios. Mr. Campos said these were packaged at the New Building Transfer Hopper. On or about 3/4/09, Setton submitted three samples to (b) (4) two to (b) (4) and one to (b) (4) for roasted/salted in-shell pistachios with FMO# 0548B06 Lg-1. One of the samples that was analyzed by (b) (4) in (b) (4) detected *Salmonella* on 3/12/09. The other two samples tested negative. Setton

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has the product on hold at their firm for re-roasting and resampling. Again, the sample was split between two laboratories, as Mr. Gibbons had stated they had thought that there maybe a problem with the (b) (4)

Ms (b) (6) provided us with the following copies of records for this FMO/Lot:

- o 2/20/09 Hand-sort records, Exhibit #22 pages 1-2.
- o 2/26/09 FMO Certified Tracking sheet; I was told this is a new record, Exhibit #22 page 3.
- o 2/28/09 roasting log for Planters 21/25 (no FMO/Lot noted), Exhibit #22 page 4.

(Firm management said this FMO/Lot was packed at New Building Transfer Hopper around 2/26/09 but must be around 2/28/09 since they provided roasting log dated 2/28/09)

- o 3/7/09 (b) (4) COA for negative *Salmonella* Lab ID (b) (4) Exhibit #22 page 6.
- o 3/12/09 (b) (4) COA for positive *Salmonella* Lab ID (b) (4) (isolate link), Exhibit #22 page 7.
- o 3/6/09 (b) (4) COA for negative *Salmonella* Lab ID (b) (4) Exhibit #22 page 5.
- o 3/12/09 dated hold tags indicating hold for re-roasting and retesting, Exhibit #22 pages 8-9.

On 4/9/09 Ms (b) (6) said the packaging log and Quality Inspection Sheet could not be located for this FMO/Lot. Thus, the packaging date is an estimate. Since the firm's management could not give us a verified production date, determination of what type of product was produced prior to this FMO/Lot could not be determined and also the related sanitation that was performed could not be determined.

Mr. Aguilera said they took the proper corrective actions by placing the product on hold to be re-roasted and retested. At this time (March 2009), the firm still was not testing for *Salmonella* for all their FMO/Lots being shipped to their other customers (other than (b) (4) and the (b) (4) other customers that are listed in Exhibit #71 who require microbiological testing).

5) FMO 0578 W/M Cal R/S (DOC 501603) - Lab ID (b) (4) (isolate link)

(b) (4)

2 Samples → (b) (4) → Negative → Shipped to Kraft related firm
 → Positive (too late, already shipped, Kraft is holding)

Mr. Gibbons said the sample was also split between two laboratories since they thought that there was a problem with the laboratory they were using in (b) (4). These were roasted/salted whole kernel pistachios packed at the South Hand-sort into (b) (4) lb. (b) (4)

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(b) (4) On 3/6/09, the firm submitted two samples to (b) (4) one to (b) (4) and one to (b) (4) for roasted/salted kernels with FMO# 0578 W/M packed in (b) (4). On 3/12/09 the firm received a negative result from the (b) (4) Laboratory in (b) (4) and in turn, they shipped the pistachios to our customer. Later that same day, they received the analysis from (b) (4) with a positive *Salmonella* result. Ms. (b) (6) explained to me that these pistachios were already in-route to their customer when they received the positive *Salmonella* result. The Bill of Lading Order Number (b) (4) (w/PO# (b) (4)) and Invoice number (b) (4) (w/PO# (b) (4)) shows Setton sold and shipped the Roasted/Salted Pistachios Kernels (FMO# 0578W/M) to Kraft/Planters (b) (4). Setton informed us that these pistachios are on hold by Kraft. It could not be determined if Kraft also received the positive laboratory report for this lot prior to their visit on 3/24/09 and not simply the negative result, since the PowerPoint presentation (Attachment A) is silent regarding this.

The following copies of records were collected from Ms. (b) (6)

- 3/6/09 FMO tracking log for FMO 0578, Exhibit #23 page 1.
- 3/12/09 (b) (4) COA record with Lab ID (b) (4) Exhibit #23 page 6.
- 3/12/09 (b) (4) COA record with Lab ID (b) (4) (isolate link), Exhibit #23 page 7.
- 3/6/09 Quality Analysis Certificate for FMO 0578 W/M/release (b) (4) Exhibit #23 page 2.
- 3/6/09 Quality Analysis Certificate for FMO 0578 W/M/release (b) (4) Exhibit #23 page 3.
- 3/12/09 B/L with order # (b) (4) (isolate link) to Kraft Planters in (b) (4) Exhibit #23 page 4.
- 3/13/09 invoice to Kraft/Planters in (b) (4) Exhibit #23 page 5.

Ms. (b) (6) could not locate the production/QC records (Packaging Line/Quality Inspection Sheet) to determine the packaging date. She gave the best date as noted on the Quality Analysis Certification sheet. Since the firm's management could not provide a verified production date, it could not be determined what product was produced prior to this FMO/Lot and whether any related sanitation was performed.

After the firm received the fifth and sixth finished product confirmed positive sample analysis results for *Salmonella* on 3/12/09, records show about (b) (4) environmental samples were analyzed by the (b) (4) for *Salmonella* and all were negative, (Exhibit #32 with dates 3/17/09). The spreadsheet (Exhibit #75) provided by Setton Pistachio listing (b) (4) samples after the six confirmed positive (3/12/09) did not show that any finished pistachios were analyzed for *Salmonella* by (b) (4) in March 2009 prior to our inspection on 3/26/09. The firm did not attempt to expand testing of other FMO/Lots for other customers who did not require *Salmonella* testing. Setton continued to produce and ship its pistachio products with no changes in its sanitation and microbiological quality control procedures

until the FDB/FDA inspection was initiated on 3/26/09. The firm halted packaging of its pistachios (other than raw in-shell going for export) and hired consultants to enhance its microbiological sampling, sanitation, processing and tracking programs.

Ms. (b) (6) had her own spreadsheet for these positive samples, Exhibit #50 pages 1-5 (page 5 is the initial timeline). Ms. (b) (6) created 4 revisions of the spreadsheet during the course of the inspection to reflect the records she provided to us. Exhibit #50 page 1 is her last version of the timeline.

GNC AND SANFILIPPO TRACEBACKS

The spreadsheet in Attachment P summarizes the information collected for the FMO/Lots to GNC (2147 W/M 22028 R/S-2018, 2948 W/M 29728 R/S-2018, 3088 W/N 31128 R/S-2018, 3088 W/N 31218 R/S-2018, 3088 W/N 31518 R/S-2018) and to Sanfillippo (2407 W/M 28718R-2014, 2507 25828R-2014). The (b) (4) COA's for GNC were negative.

Please note that the trace backs for three of the FMOs/Lots found that they included pistachios from the firm's 2007 crop.

- FMO/Lot 2147 W/M 22028 R/S-2018 consisted of pistachios from the 2007 crop and packaged in the 2007 crop year on 8/6-7/08.
- FMO/Lot 2507 25828R-2014 was pistachios from the 2007 crop packaged in the 2008 crop year on 9/13-14/08.
- The trace back to FMO/Lot 2407 W/M 28718R-2014 found that the pistachios in this lot were the 2007 crop packaged in the 2008 crop year on 10/13/08.

The following FMOs/Lots' interstate shipments were documented in the following FACTS collection reports:

- 2948 W/M 29728 R/S-2018 is documented in FACTS sample #501604.
- 3088 W/M 31218-R/S-2018 is documented in FACTS sample #501605.
- 2407 W/M 28718R-2014 is documented in FACTS sample #501606.
- 2507 25828R-2014 is documented in FACTS sample #501607.

The trace back records to these four FMO/Lots are in Exhibit #76-77 & 87-88. See heading titled, Samples Collected, of this inspection report, below for more information (on page 87).

FMO/Lot 0588 D05XLA-2 was added to this spreadsheet (Attachment P) since part of the FMO/Lot was shipped out of state (Exhibit #84 page 3). It was one of the 22 finished

products sampled by the firm after the initiation of this inspection. Three others (out of the 22 finished products) tested positive, but no interstate commerce existed. See the next subsection below on these 4 positives (on page 59).

The trace back to these four FMO/Lots had more traceable records than the 5 positives that the firm had knowledge about. Thus, a narrative for each of these FMO/Lots is not included in this inspection report since the spreadsheet (Attachment P) and records (production, the production before and closest sanitation record, invoice and shipping) in Exhibit #76-77 & 87-88 are self explanatory.

Four Positive Finished Products Sampled by the Firm After Initiation of the Inspection

The firm began sampling finished pistachio products after initiation of this 3/26/09 inspection. There were 21 finished product samples collected after our inspection began and four of the samples were positive for *Salmonella* (Exhibit #94, pages 1, 11 & 13 and Exhibit #95, page 8). The table below shows the four products that tested positive.

The 14 finished products that Setton sent to (b) (4) were later transferred to (b) (4) since the (b) (4) laboratory was busy, Exhibit #94. These were analyzed by (b) (4). The isolates were later sent to the FDA laboratory in Arkansas. The (b) (4) results for the three positives are in Exhibit #78.

The (b) (4) laboratory result for the positive composite is in Exhibit #95 page 8. There were four lots that went into a composite that (b) (4) analyzed that was positive for *Salmonella*. The lot(s) in the composite that were positive(s) could not be determined by record review.

FIRM'S POSITIVES SAMPLES	Product	Packed	Date Packed	FMO #	Box #	ID #
1 Elliens 0548 D05LgB-5	R/S	Line (b) (4)	3/18/2009	0548D05 LgB-5	4	(b) (4)
2 0588 D05XLA-1,2 Costco Box1	R/S	(b) (4)	3/18, 19, 20, 23/09	0588D05XLA-1,2	1	(b) (4)
(b) (4)						
4 Composite analyzed by (b) (4)						
(b) (4)						
The fourth positive was from a composite of four lot of finished products.						
Records collected and reviewed but determination of which lot was suspect could not made						

FMO/Lot 0588 D05XLA-2 was added to the spreadsheet in Attachment P since part of the FMO/Lot was shipped out of state (Exhibit #84 page 3). FACTS sample #501608 documented the interstate shipment of that lot. The other 3 positive finished products had only interstate commerce for the incoming (b) (4) field-picked pistachios being commingled in the firm's pistachio process, Exhibit #40.

The firm increased its *Salmonella* environmental testing after (b) (4) 3/24/09 visit. About (b) (4) environmental samples were taken and submitted to (b) (4) (Exhibit #34 & 35). In

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that (b) (4) environmental samples, Setton also had (b) (4) collect about (b) (4) environmental samples and had (b) (4) analyze these environmental samples before the FDA/FDB inspection was initiated on 3/26/09 (Exhibit #34 pages 1-11). Mr. Cohen said they are now collecting (b) (4) g subs per lot for *Salmonella* analysis (see the heading below titled, "General Discussion with Management" of this inspectional report for more information, on page 82).

Water sources

The firm uses (b) (4) water sources: (b) (4) water for the production process (b) (4) (b) (4) water for the silo side of the processing areas. The firm uses (b) (4) provided water as an ingredient and also to clean the processing equipment and lines. The firm depends on (b) (4) for checking, monitoring and maintaining its drinking water quality, Exhibit #51.

Mr. Aguilera said the (b) (4) water on the incoming field harvesting side of their processing (before the silos and to clean the silos) is (b) (4) water from the surface water of the (b) (4). He provided the last (b) (4) report for the water which shows it is non-treated water and does not meet the standards for drinking water (Exhibit #51 page 5). Mr. Aguilera said prior to and during peak season, the firm treats this water by (b) (4) it and checking the (b) (4) levels (b) (4) at the (b) (4) and at times it is checked (b) (4) a day. He does not maintain records of these checks. Mr. Aguilera said their target is (b) (4) ppm and when the (b) (4) gets around (b) (4) ppm they add more (b) (4). They do not use any type of automatic continuous monitoring of this (b) (4) water that they (b) (4). The firm was not currently (b) (4) and using this (b) (4) water on the silo side, since it is not currently pistachio harvesting season and this (b) (4) water was not currently available. Mr. Aguilera said they have not had the (b) (4) water microbiologically analyzed.

MANUFACTURING CODES

The following section on manufacturing codes was reported by Investigator Hamaoka. The firm uses a two coding system (FMO and in-house tracking) for their manufacturing code. Also, a Best Before date maybe included with the manufacturing code for the firm's retail products and other customer requested products.

FMO Number:

Mr. Gibbons (Plant Manager) informed us that the FMO tracking number in their manufacture code is mandated by the Federal Marketing Order that monitors aflatoxins in pistachios. He explained that every 150,000 lbs (or can be less but not more) being distributed domestically has to be assigned an FMO (Federal Marketing Order) number,

which in this case is 150,000 lbs. of pistachios; sub samples are collected to be analyzed for aflatoxin.

Mr. Campos (Production Supervisor) explained the FMO number breakdown. He said the FMO numbers are formed when the pistachios are (b) (4) The sorted and/or sized pistachios are drawn from either (b) (4) to make around the 150,000 lbs of pistachios.

- o The FMO number is then assigned when around 150,000 lbs is made on the (b) (4)
- o The firm then (b) (4) (b) (4) Mr. Campos said they have (b) (4) Thus, there has (b) (4)
- o If the pistachios are kernels, a (b) (4) (b) (4) number. The firm next (b) (4) This Lot number is explained below in the next subsection, In-house Lot tracking number.
- o If the product is in-shell, (b) (4) (b) (4)
- o The (b) (4) (b) (4)
- o (b) (4)

For example for in-shell pistachios with FMO 2818 C03 LGB-2

- o The (b) (4) indicates when the (b) (4) (b) (4)
- o The (b) (4)

For example for shelled pistachios (kernels) with FMO 2407 W/M

- o The (b) (4) (b) (4)
- o The (b) (4)
- o The (b) (4)

In-house Lot Tracking Number:

The next series of the manufacture code that a product can have is the firm's in-house lot number which indicates (b) (4). For example, for the in-house lot number: 28718R-2014

- o The (b) (4) (b) (4)
- o The (b) (4)
- o The (b) (4)
- o The (b) (4) would represent (b) (4) represents (b) (4) would represent (b) (4)
- o The (b) (4)

Please also note:

- o If there is an (b) (4) (b) (4)
- o If the product was (b) (4) (b) (4) (b) (4) (b) (4)
- o If the (b) (4) (b) (4)
- o (b) (4) (b) (4)

Best Before Date:

Mr. Campos said the shelf-life or Best Before date that the firm uses for its pistachios is 1-year from the date of packaging.

Mr. Aguilera provided Exhibit #79 of the firm's manufacturing code breakdown.

The firm does maintain a library/retain sample for each lot. (b) (4) pounds are collected for each customer order. The retain samples that are over (b) (4) months from packaging are discarded. Thus, there were no available samples to collect at the firm related to the Costco complaint (discussed in next heading, Complaints (on page 63, below) and the FMO/Lot to the GNC and Sanfilippo related trace backs (on page 58).

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COMPLAINTS

The following section was reported by Investigator Hamaoka. The firm had one complaint in FACTS since the previous inspection (Attachment Q). After reviewing this complaint with management, Jeffery Gibbons, Plant Manager, said that they are not familiar with this complaint but will respond to it. The next day he provided me with Exhibit #80 which he said they review their records and this product was packed in November 2008 and there was no product available of the same lot for collection.

DATE DISTRICT COMP #	PRODUCT CODES	PROBLEM	FIRM'S RESPONSE
1/21/09 SEA-DO 73148	4 lbs Kirkland California Pistachios/VIN 63857 NOV 14 2009	Family members who ate pistachios got sick. One member did not eat and did not get sick. Ate on 1/11/09 and got sick on 1/12/09. Abdominal cramps & diarrhea 18-24 hours w/nausea, headache & vomiting	No other complaints. VIN 63857 is not a lot code but Setton found by the Best By Use date. Mgt said no roasting records maintained in Nov. 2008. Thus, could not verify roasting temperatures. Exhibit #80 consists of the records Mr. Gibbons provided in response to this complaint. SEADO later collected a sample and it was NAI.

Mr. Gibbons said he was in charge of complaints. He said customer complaints are initially handled by Setton International Foods, Inc. in Commack, NY and they are forwarded to him if they involve the Terra Bella facility and he would research each complaint. He said they receive mostly complaints involving quality issues such as insect damage and shell fragments in the pistachios. Then Mr. Gibbons talked about a complaint of an upset husband calling to obtain cash compensation claiming his wife was self-employed and got sick for a couple of days. I asked him for the file of this complaint and their response to this complaint. Mr. Gibbons said the husband just wanted compensation so it was not filed. He said there is no complaint file and I requested the ones routed to them from New York and he informed me these could be still on peoples' e-mails. I asked FDB Investigator Bloxsom to obtain the firm's complaint file. She talked to Mr. Gibbons and was informed there was no complaint file. See the heading below in this inspection report titled Refusals for more information (on page 81).

After asking Mr. Gibbons, on 4/30/09 Mr. Cohen said there was a complaint file. I informed him that I had previously requested their complaint file. He informed me they have not received any illness complaints. I informed him that I requested the complaint file

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and my request was not simply for illness complaints. Records of complaints were requested on the 414 Attachment to the FDA 482c (Request for Records) issued to the firm and they were not provided to us; see the 414 Attachment to FDA 482c attached to this report.

RECALL PROCEDURES

The firm has written recall procedures (document number 3.11: 1/8/2009) (See Exhibit #81). The recall procedures document consists of an overview, procedure for recall and trace back of product, product hold procedure, rework handling procedure, quality control hold tag, and quality control release tag. The recall team leaders are Jeff Gibbons, Agustin Gonzalez, and Nick Lapietra. Mock product recalls are conducted (b) (4) times a year. A randomly selected mock recall is in Exhibit #14.

For the pistachio recall covered during this inspection, see headings titled Summary (on page 3), History (on pages 10, 14, 19 & 21), Voluntary Corrections (on page 105), and Attachment D, E, F, G, H, I & J in this report. Master electronic file (on a CD-R) of the bill of ladings for the voluntary recall are in Exhibit #91. The actual paper copies of the bill of ladings, a copy of the electronic file (on a CD-R) with the bill of ladings and the actual recalled product labels were provided to SAN-DO's recall coordinator.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

On 4/30/09, the discussion with management meeting was held with Nicolo (NMI) Lapietra (General Manager), H. Lee Cohen (Production Manager of Setton International Foods, Inc.), Jeffery J. Gibbons (Plant Manager), (b) (6) (Office Clerk), Octavio (NMI) Campos (Production Supervisor) and Frank G. Aguilera (Quality Supervisor). The FDA 483, Inspectional Observation, was issued to Nicolo (NMI) Lapietra, in the absence of Joshua J. Setton (President/CEO of Setton Pistachio of Terra Bella and Setton International Foods, Inc.). Each FDA 483 item was read and discussed with the firm's management. The following section was reported by both Investigators Buckalew and Hamaoka.

Observations listed on form FDA 483

OBSERVATION 1

Failure to manufacture, package, and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

After receiving sample analysis results for your roasted pistachio products that were

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positive for *Salmonella* beginning in October 2008, your firm continued to process roasted pistachio products under the same processing conditions until March 2009. Your firm continued to distribute roasted pistachio products after the first private laboratory sample of your roasted pistachio product was reported positive for *Salmonella* and did not evaluate the adequacy of your roasting process to assure that your roasted pistachio products were free of microorganisms of public health significance. Your firm also did not attempt to determine potential routes of cross contamination within your facility between raw pistachios and roasted pistachios after your firm began receiving positive *Salmonella* sample results for your roasted pistachio products.

The private laboratory testing that your firm requested found *Salmonella* in your processed In-Shell Roasted/Salted Pistachios which was the product (b) (4) pounds) your firm shipped on 10/14/08 to an out-of-state customer under Bill of Lading Order Number (b) (4) (w/PO# (b) (4)), FMO number 2818C03LgB-3 (as stated on the bill of lading), prior to your firm receiving the private laboratory analytical results. The same In-Shell Roasted/Salted Pistachio product was returned by the aforementioned customer to your firm. Your firm then re-roasted the product and blended it into other pistachio products which were sent to other customers.

On 3/12/09, your firm shipped to an out-of-state customer your processed Roasted/Salted Pistachio Kernels (b) (4) pounds) under Bill of Lading Order Number (b) (4) (w/PO# (b) (4)), Invoice number (b) (4) (w/PO# (b) (4)), and FMO number 0578W/M which your private laboratory testing found positive for *Salmonella*.

On 3/18/09, your firm shipped to an out-of-state customer your processed In-shell Roasted/Salted Pistachios (b) (4) pounds) under Bill of Lading Order Number (b) (4) (w/PO# (b) (4)) FMO number 0588D05XLA-2). A sample of this product was collected and sent by your firm to a private laboratory for testing and found positive for *Salmonella* after your firm had shipped the product.

There were at least eight reported *Salmonella*-positive test results, on samples submitted by your firm of your roasted pistachios, from four third-party private laboratories from October 2008 through March 2009.

Your firm lacks adequate quality control operations and a planned/systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the FD&C Act. When your firm was notified by your private laboratories of sample test results for your roasted pistachio products that were positive for *Salmonella*, your firm did not have procedures in place to assess the most appropriate response to these reported positive samples.

On 3/28/09, a large gap leading to the outside environment as large as 6" x 1 foot, was

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observed in the roof of your firm located above the (b) (4) roaster used to process pistachios (b) (4). There was a rusty and broken part of the ceiling hanging from this gap. There were two other gaps leading to the outside environment observed, as large as 2" x 6", in this ceiling above the (b) (4) roaster. Thick layers of dust and debris were observed on the red ceiling structures and over head pipes in the packaging room.

Reference: 21 CFR 110.80(b)(2)

Supporting Evidence and Relevance:

- DOC 501602 for in-shell roasted salted pistachios with FMO 2818 C03LgB-2 (FACTS collection report attached to this inspection report)
- DOC 501603 for in-shell roasted salted pistachio whole kernels with FMO 0578 W/M (FACTS collection report attached to this inspection report)
- DOC 501608 for in-shell roasted salted pistachio kernels with FMO 0588 D05XLA-2 (FACTS collection report attached to this inspection report)
- Exhibit #19 pages 10 & 15 are the positive *Salmonella* results for FMO 2818 C03LgB-2 by two private laboratories.
- Exhibit #23, page 7 is the positive *Salmonella* result for FMO 0578 W/M by (b) (4)
- Exhibit #78, page 3 is the positive *Salmonella* result for FMO 0588 D05XLA-2 by (b) (4)
- Exhibit #19 pages 1-4 & 13 are the production record and their employee affidavit (Confirmation of Re-Roast by Mr. Campos) for FMO 2818 C03LgB-2 that the firm provided during this inspection.
- Exhibit #23 pages 1-3 are the production records for FMO 0578 W/M that the firm provided during this inspection.
- Exhibit #84 pages 5-15 & 26 & 34 are the production records for FMO 0588 D05XLA-2 that the firm provided during this inspection. The label to the product is in Exhibit #74.
- Discussion of the firm's microbiological procedures are in this inspection report in the above heading, Microbiological (on page 45).
- Discussion on the five positive *Salmonella* samples, the 10/14/09 (FMO/Lot 2818) shipment and the 3/12/09 (FMO/Lot 578 W/M) shipment are in the above heading, Microbiological, *The Five Positive Salmonella Results that Setton Received and Had Knowledge* (beginning on page 48) and the time of events to these five positive are at the beginning of the timeline in the above heading of this report, *Timeline of Some of the Events Related to this Inspection* (on page 12).
- More discussion on the 3/18/09 (FMO/Lot 0588 DO5XLA-2) shipment is in the above heading, Microbiological, *Four Positive Finished Products Sampled by the Firm After Initiation of the Inspection*, of this inspection report, on page 59.

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- The photograph of the holes in the roaster room's roof are in Exhibit #59 pages 1-3 and also this is discussed in this report in the above heading, Operations, *Process for the Pistachios Inside the Processing Building* (on page 36).

The firm has over (b) (4) customers (Exhibit #42) and the firm does finished product testing for (b) (4) customers (Exhibit #71). (b) (4) is one of those (b) (4) customers and according to the firm's management there were (b) (4) shipments (b) (4) lbs each) to Kraft from September 2008 through February 2009. Of these (b) (4) shipments, two tested positive for *Salmonella* (Exhibit #19 & 23).

Mr. Gibbons said the roasting process (i.e., time and temperature) was based on their customers' preferences regarding quality factors for the final pistachio product. He stated he believes the roasting time and temperatures his firm has been using is a sufficient kill step for *Salmonella* microorganism. See also page 36, paragraph beginning with Mr. Gibbons.

The firm did not evaluate the adequacy of their roasting process as they did not initiate a roaster validation study until March 2009 and continued to process and distribute the nut products prior to that time.

The firm did not attempt to determine the possible routes of contamination in their processing facility until after their customer audit of March of 2009. They continued to process and packed raw and roasted products on the same lines and equipment until their customer audit, Exhibit #39.

There were no records to show what time and temperatures were used to re-roast pistachios prior to 1/9/09. Mr. Aguilera and Mr. Campos both stated that FMO #2818C03LgB-3 that was processed in October 2008 was re-roasted and blended into other pistachio products that were sent to other customers. Mr. Campos said they started maintaining roasting records on 1/9/09. A review of these records revealed that the FMO/lot numbers were not on the roasting records to enable a determination regarding what product was being roasted.

Pistachios that are adulterated should be disposed of in a manner that protects against the contamination of other food. If the adulterated pistachios are capable of being reconditioned, they should be reconditioned using a method that has been proven to be effective or they should be re-examined and found not to be adulterated before being incorporated into other food.

Investigator Fernandez observed the gap in the roof above the (b) (4) roaster on 3/28/09 that opened to the sky. The gap in the roof was above where the roasting of the

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pistachios occurred. The roasters are not fully enclosed as the east and west sides of roasters were observed to have exposed product and exposed food contact surfaces when pistachios were being roasted on 3/27/09. Investigators Buckalew and Hamaoka observed birds in various areas around the firm (raw silos, east of the processing buildings and across the street); also the firm's audit report noted bird activities, Exhibit #16, pages 55 and 56.

It is the food processor's responsibility to be familiar with the rules and the cGMP regulations for the foods they produce so that they are safe, clean and wholesome which includes:

- It is a prohibited act to ship adulterated food products across state lines.
- Implementing adequate quality control operations and sanitation controls to ensure that the foods produced are suitable for consumption.
- Keeping potential contaminants in raw materials separate from the final food is required by the cGMPs for foods.
- The blending of any adulterated food with other lots of food makes the final food product adulterated.
- Keeping processing areas clean and in good repair to prevent foods from becoming adulterated.

With the US FDA positive *Salmonella* sample results representing four different areas of the processing plant (Exhibit #85, page 3) and the eight positive *Salmonella* lots detected by the firm's private laboratories (three of the eight were examples in Observation 1 of the FDA 483-Inspectional Observations), they collectively show that the firm's food processing equipment and the environment of the firm's processing facility is contaminated with *Salmonella*. This shows that the firm's processing facility has an on-going source of contamination for the pistachios that pass through its processing lines.

The four different areas showing *Salmonella* contamination exhibited in Exhibit #85 were: 1) incoming un-roasted area (INV 489158), 2) Red Dye Packaging (INV 529672), 3) roasting room (INV 482178) and 4) the sheller room (INV 490163). The three environmental samples were positive in areas where food and food contact surfaces are exposed in these rooms (i.e., incoming un-roasted area, Red Dye packaging and roasting room). The firm produces ready-to-eat pistachios and nut products.

The incoming un-roasted area is where the un-roasted pistachios enter the processing building to be sorted and sized. The employees' restrooms and lunch room were located in this area.

The Red Dye packaging is where roasted pistachios are dyed red or flavored. The roasted pistachios can come from the roaster or from Bulk

Line (b) (4) where the roasted pistachios are packed in 25 lbs cases. Later the 25 lb cases of roasted pistachios are (b) (4) onto the Red Dye packaging room. When the roasted pistachios come from the roaster, they (b) (4)

being (b) (4) Mr. Aguilera informed Investigator Hamaoka that the finished product that tested positive (INV 529672) by FDA was (b) (4) from 25 lb cases that (b) (4) were packed in the packaging room. The packaging room had Bulk Line (b) (4) packaging equipment that packaged raw and roasted products. The firm's management identified Bulk Line (b) (4) as shared equipment to us (Exhibit #85, page 2). The firm routinely packaged roasted ready-to-eat pistachios in the same packaging room as their un-roasted pistachios.

The roasting room is where the (b) (4) and (b) (4) roasters are located which had not been validated for a microbiological kill for *Salmonella*. There were (b) (4) hoppers in the roasting room (b) (4) for each roaster where un-roasted pistachios are dumped in the hoppers prior to being roasted. The roaster room did not have controlled ventilation system to direct positive air flow.

The firm sheller room is the area where the raw pistachios are shelled to be made into kernels that are later sorted and sized then either packaged raw or roasted and packaged. At times, the roasted kernels can be sorted again after being roasted and were at times sorted on the same sorted table where raw kernels were sorted. The firm identified this as shared equipment (South Sorter), Exhibit #85 page 2.

Bins were shared with roasted and un-roasted pistachios without any controls in place to verify if they were cleaned/sanitized or if cleaned, adequately cleaned and sanitized. Also, forklifts, sampling carts and brooms were not dedicated to the roasted or the un-roasted areas of the plant.

Discussion with Management:

Harris (Lee) L. Cohen stated his company took action by bringing in (b) (4) to do environmental swabs and increased the pistachio product sampling size for (b) (4). He stated his company did their own environmental swabs. All environmental swabs were negative. Mr. Cohen stated his company had shipped Kraft roasted pistachio product by a waiver agreement with Kraft. Mr. Cohen stated when they became aware of the pistachio product that tested positive for *Salmonella*, they had Kraft ship it back to them and then they re-roasted and tested the pistachios after roasting which tested negative for *Salmonella*.

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FDA Investigator Hamaoka informed Mr. Cohen that his upper management staff said the firm's customer (b) (4) increased the sampling size for *Salmonella*. Mr. Cohen then asked his upper management personnel who were present and they confirmed that it was (b) (4) that increased the sampling size for the required *Salmonella* testing and not the firm (Setton).

Mr. Cohen stated the 3/12/2009 (FMO #0578 W/M) pistachio shipment was tested by (b) (4) different laboratory sites. (b) (4) of the laboratory analyses stated the product was negative for *Salmonella* while one of them stated the product was positive for *Salmonella*. He stated Kraft now has the pistachio product on hold and none of it was consumed.

Mr. Cohen stated the 3/18/2009 (FMO #0588D05XLA-2) pistachio product shipment was not tested because it was not requested by that customer. Mr. Cohen stated the company's recall stopped all shipments from his firm. He stated the product they found positive was in inventory under their firm's control and was not released.

Mr. Cohen claimed that there were not eight reported *Salmonella* positives since some were tests of the same lot and these were double counted. Investigator Hamaoka verbally outlined the eight positives by private laboratory testing that the FDA 483 referenced.

1. FMO/Lot 2818CO3LgB-2 packed on 10/7/08 and repacked on unknown dates while being blending into other different products and distributed to unidentifiable customers.
2. FMO/Lot 347B14LgB-2R packed on 12/19/08 and repacked on 2/11-12/09
3. FMO/Lot 0418 W/M (0338) packed on 2/3/09
4. FMO/Lot 0548B06 Lg-1 packed on an estimated date of 2/26/09
5. FMO/Lot 0578 W/M packed on estimated date of 3/6/09
6. FMO/Lot (b) (4) packed on 3/18/09
7. FMO/Lot 0588D05XLA-1, 2 packed on 3/18-20, 23/09
8. FMO/Lot 0588D05XLA-2 packed on 3/13, 16-18/09

The first five *Salmonella* positive results are discussed in the heading, *Microbiological, The Five Positive Salmonella Results that Setton Received* (on page 48), of this report. The next 3 *Salmonella* positive results are discussed in the above heading, *Microbiological, Four Positive Finished Product Samples by the Firm After Initiation of the Inspection* (on page 57) of this report. The related FACTS collection reports and related exhibits to the positive private laboratory tests are in these sections of the report.

Mr. Cohen stated that the entire roof had been replaced. Investigators Buckalew and Hamaoka observed on the last day of the inspection on 4/30/09 that the gap above the (b) (4) roaster had been repaired. We did not observe a replacement of the entire roof

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from outside the plant. He said that a deep cleaning had taken place using lift cranes to remove all dust from beams and other structures including the ceilings and walls. Mr. Cohen stated additional steps had been taken to update the dust collection system such as (b) (4). He stated the facility will have a deep cleaning every (b) (4) months. Mr. Cohen stated that air handling equipment has been placed outside, more vacuuming equipment is now available (sucking in air verses shooting out air) and the (b) (4) from the roaster will be extended.

Investigator Hamaoka inquired as to the type of deep cleaning being referenced and when this took place. Mr. Cohen replied about (b) (4) ago they performed a deep cleaning that was removing the dust, using a degreaser, sanitizer, cleaned the ceiling and railings using elbow grease to clean. When Investigator Hamaoka inquired about the packaging equipment, he said the packaging equipment was cleaned with a water based cleanser and then sanitized.

Also, Investigator Hamaoka discussed with Mr. Cohen, Mr. Aguilera, Mr. Gibbons, Mr. Campos and Ms. (b) (6) that we understood that they will be holding (b) (4) treating and/or roasting any positive lots but they need to have adequate corrective action(s) in place for the other suspect production runs that ran before and after the positive lot. They need to clean/sanitize the suspect processing lines and equipment that the positive lot was produced on and verify these corrective actions when a positive *Salmonella* result occurs. No comments were made by the firm's management. They were told they need to think about the appropriate corrective actions in the event of a positive test result for environmental samples and/or finished products.

OBSERVATION 2

Raw materials which contain levels of microorganisms that may produce food poisoning or other disease are not pasteurized or otherwise adequately treated.

Specifically, your firm lacks adequate controls to assure that your roasting step is effective in destroying microorganisms of public health significance. There is no assurance that your roasting process is effective and that any of your roasted pistachios are pathogen free.

Prior to January 2009, your firm did not monitor roasting temperatures, the length of time the pistachios were exposed to heat or the depth of the pistachios on the conveyor belts that are processed through the roasters. Your firm has not calibrated your roaster temperature monitoring devices or the belt speeds of the roaster conveyor belts. The in-shell and kernel pistachio roasters are used to roast raw pistachios and also used to roast previously roasted lots of pistachios that were tested by your private laboratories and found to be adulterated with undesirable microorganisms of public health significance.

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Reference: 21 CFR 110.80(a)(2)

Supporting Evidence and Relevance:

- These observations are discussed in this report in the above heading, *Operations, Process for the Pistachios Inside the Processing Building* (beginning on page 36).
- Positive *Salmonella* tested pistachios with FMO/Lot 2818C03 LgB-2 are one of the FMO/Lots found where the firm re-roasted and distributed the pistachios. This is discussed in the above heading *MICROBIOLOGICAL, The Five Positive Salmonella Results that Setton Received* (on page 50). FACTS DOC 501602 was collected and attached to this inspection report. (b) (4) Certificate of Analysis for the positive *Salmonella* result is in Exhibit #19 pages 9-10 (Lab ID (b) (4) and (b) (4) positive *Salmonella* result also for this same FMO/Lot is in Exhibit #19 page 11 (ref # (b) (4)). The isolate was collected at (b) (4) Laboratory and forwarded to US FDA Laboratory (under INV 531954 with (b) (4) ref # (b) (4)). (b) (4) no longer had the related sample isolate.
- Positive *Salmonella* tested pistachios under FMO/Lot 3478B14 LgB-2R are another FMO/Lot that was found positive for *Salmonella* where the firm re-roasted and distributed the pistachios. This is discussed further in the above heading *MICROBIOLOGICAL, The Five Positive Salmonella Results that Setton Received* (on page 53). The (b) (4) COA for the positive *Salmonella* results is in Exhibit #20 page 3 (Lab ID (b) (4)). This isolate was forward to the US FDA laboratory under Lab ID (b) (4) (isolate link). After these pistachios were re-roasted, they were repacked and shipped to Hong Kong.
- Positive *Salmonella* tested pistachios with FMO 0548B06 Lg-1 is where the firm had on its hold tag that these positive *Salmonella* tested pistachios would be re-roasted (on page 55). Exhibit #22 pages 8-9 indicate on the (b) (4) COA with Lab ID (b) (4) that these pistachios were positive for *Salmonella*. FACTS collection report DOC 538400 covers a shipment of pistachios delivered from (b) (4) prior to the processing of FMO/Lot 0548B06 Lg-1. The related isolate to this sample was forwarded to US FDA laboratory under Lab ID (b) (4) (isolate link).

Every food manufacturer needs to do their part in preventing their foods from being contaminated with food borne pathogens and not rely on customers to detect and eliminate food borne pathogens.

Equipment and identified critical control points (i.e., time and temperature) need to be properly validated and verified to effectively control the growth of microorganisms. Critical control points (i.e., time and temperature controls) need be monitored and verified (i.e., properly reviewed by properly trained individuals) to assure that microorganisms of

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public health significance are destroyed or prevented from growing. This ensures that the proper control of time, temperature and bed depth on the roaster's conveyors are maintained. Maintaining some type of verification (i.e., record) assists in ensuring the pistachio production is free from contaminants and microorganisms especially re-roasted pistachios that previously tested positive for *Salmonella*. This facilitates in ensuring that the food products are produced adequately. Maintaining the calibration of instruments monitoring the critical control points is crucial in preventing, eliminating or reducing the food contaminations.

For the first two positive samples (10/21/09 & 1/8/09), Mr. Aguilera said the firm used re-roasting as a corrective action for these two FMO/Lots that tested positive for *Salmonella*, yet they had not validated their roasters, not calibrated the roaster monitoring devices and roasting records were lacking. They did not begin maintaining roasting records until January 2009. A review of the roasting records (January and later) revealed that Setton did not record the FMO/Lots processed through the roaster.

Discussion with Management:

Mr. Cohen stated the validation of roasters to function as a kill-step is on-going. Mr. Cohen stated the validation will be confirmed by a State of California certified third party. Mr. Cohen stated that his company had already installed (b) (4) in the roaster with each roaster having (b) (4). Additionally, Mr. Cohen stated that (b) (4) will monitor roaster temperatures remotely so that (b) (4) can observe the roasting parameters on the computers. Mr. Cohen stated there would be (b) (4) per roaster. For the cashew oil roaster, according to Mr. Cohen, a (b) (4) monitoring will be installed but it has not arrived yet. They will also have in their SOP that the production team will record the roaster temperatures and the supervisor will be in roasting room, monitoring and overseeing the roasting parameters.

OBSERVATION 3

Proper precautions to protect food and food-contact surfaces from contamination with microorganisms cannot be taken because of deficiencies in plant construction and design.

Specifically, your firm is not equipped with an effective air flow system to prevent cross-contamination of your finished roasted pistachio and nut products.

Reference: 21 CFR 110.20(b)(2)

Supporting Evidence and Relevance:

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- The hoppers that feed the pistachios to the roasters are located in the same room and this is discussed in this report in the above heading, Operations, *Process for the Pistachios Inside the Processing Building* (beginning on page 36).
- Where un-roasted products were packaged in the same room as the roasted products are shown in the diagram of the Roaster and Packaging Rooms of this report in the above heading, Operations, *Process for the Pistachios Inside the Processing Building* (on page 39).

The plant facility needs to provide adequate ventilation and locate and operate fans and other air blowing equipment in a manner that minimizes the potential for contaminating food, food packaging materials and food-contact surfaces. Controlling the air flow assists in preventing the cross contamination from air contaminants coming from the other processing areas, including the raw or un-roasted pistachio processing areas.

Discussion with Management:

Mr. Cohen stated the airflow is now positive in the roasted pistachio and packaging areas which pushes the air out instead of in. Mr. Cohen stated his company is adding (b) (4) (b) (4) of the roaster room. He stated all the (b) (4) that were in the roasting room and packing room have been moved outside. He stated they had sealed off (b) (4) in the (b) (4) and the ready-to-eat positive airflow now pushes air into the raw product area. Mr. Cohen stated a roof fan had been sealed off.

OBSERVATION 4

Failure to take effective measures to protect finished food from contamination by raw materials and other ingredients.

Specifically, the raw (un-roasted) pistachios and roasted pistachios were packed in the same rooms. Also, the ready-to-eat roasted pistachios were sorted in the same sort room where in-line processed raw pistachios were sorted. In addition, raw pistachios were run prior to the ready-to-eat roasted pistachios on the same equipment (i.e., roller-sorter, Bulk Line (b) (4) Transfer Hopper).

Your firm lacked adequate measures to prevent cross-contamination from the raw pistachio area to the finished, ready-to-eat roasted pistachio product area. Employees, forklifts, bins, detachable conveyor buckets, portable conveyor buckets, brooms, and sampling carts moved throughout the raw and roasted areas of the processing building.

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Your firm lacks controls in place to assure that the red dye room processing equipment was cleaned and sanitized before and after each flavored pistachio product was run. This same processing equipment is used to process flavored pistachios containing soy and wheat which are known allergens.

When 14 lots of roasted pistachio records were reviewed, it was determined that 10 of those lots had raw pistachios packed on the same packaging equipment prior to the roasted pistachio being run. Some examples are:

On 8/6-7/08, Whole Kernels Roasted/Salted Pistachios with FMO numbers 2147 W/M 21928 R/S-2018 and W/M 22028 R/S-2018 (or 08-2009) were packed on Line (b) (4). The pistachios that ran prior to the aforementioned roasted pistachios were Raw Whole Pistachio Kernels with FMO number 2147 W/M 21928R 2014 packaged on Line (b) (4) on 8/6/08. Your firm's cleaning log indicates Line (b) (4) was cleaned on 8/4, 6 & 13/08 with no time indication when the cleaning occurred.

On 10/7/08, FMO number 2818 C03 LgB-2 In-shell Roasted/Salted 26/30 Pistachios were packaged in 1700# Totes at the New Building Transfer Hopper. The product that ran prior to the aforementioned roasted pistachios was raw pistachios (18/20 US X#1) with FMO number 2748 C13XLA-1 packaged on 10/2/08 at the New Building Transfer Hopper. Your firm's cleaning logs indicate the Transfer Hopper was last cleaned on 2/16/08. Private laboratory testing found that the Roasted/Salted Pistachios, with FMO number 2818 C03 LgB-2 In-shell, was positive for *Salmonella*.

On 10/23/08, Roasted/Salted Whole Pistachio Meats with FMO 2948 W/M 29718 R/S-2018 and Roasted/Salted Pistachio Kernels with FMO 2948 W/M 29728 R/S-2018 were processed and packaged on Line (b) (4). Your firm processed and packaged raw (un-roasted) pistachios between these two roasted pistachio products. On 10/22/08, Raw Pistachios 18/20/ US Extra #1 with FMO 2888 C09XLA-1 & 2 was run on Line (b) (4). Then on the same line on 10/23/08, your firm ran Roasted/Salted Whole Pistachio Meats with FMO 2948 W/M 29718 R/S-2018. Then your firm ran Raw Pistachios 21/25 US X#1 with FMO 2698 D08LgB-1 29718R-2010. Next your firm ran Roasted/Salted Whole Meats with FMO 2948 W/M 29718 R/S-2018 followed by FMO 2948 W/M 29728 R/S-2018 both in 25 lb cases on Line (b) (4) on 10/23/08. Your firm's cleaning log indicates Line (b) (4) was cleaned on 10/20 & 29/08.

On 11/6, 7, & 10/08, your firm processed and packaged into 25# cases on Line (b) (4) Roasted/Salted Pistachio Kernels with FMO numbers: 3088 W/M 31128 R/S-2018, 3088 W/M 31218 R/S-2018, 3088 W/M 31228 R/S-2018 and 3088 W/M 31518 R/S-2018. The product that ran prior to the aforementioned roasted pistachios was Roasted/Salted Whole Pistachio Meats with FMO 2948 W/M packaged on Line (b) (4).

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on 11/6/08. The product that ran prior to the Roasted/Salted Whole Pistachio Meats (FMO 2948 W/M) was Raw Pistachios 21/25 US Extra #1 (FMO 2948 C08LgB-1) packaged on Line (b) (4) on 11/6/08. Your firm's cleaning log indicates Lin (b) (4) was cleaned on 11/5&11/08.

Reference: 21 CFR 110.80(b)(6)

Supporting Evidence and Relevance:

- Environmental FACTS sample INV 490163-sub 67 was taken from the roller-sorter (sizer) that was positive for *Salmonella*, see FACTS collection report attached to this inspection report. The roller-sorter (sizer) (stored in the sheller room where un-roasted pistachios were shelled) was used to package roasted and un-roasted finished pistachios.
- Environmental FACTS sample INV 482179 was the finished product that was processed in the Red Dye room that was positive for *Salmonella*, see FACTS collection report attached to this inspection report. Any type of verification for the cleaning of the Red Dye line was requested initially were random (b) (4) checks and not necessarily the Red Dye line, Exhibit #63. Then cleaning records for the Red Dye line were requested. The firm's management said there were none for the 3/17/09 time frame.
- The Red Dye room, hoppers to the roasters being in the same room, shared bins, conveyors, forklifts, employees, brooms and sampling carts are discussed in this report in the above heading, Operations, *Process for the Pistachios Inside the Processing Building* (beginning on page 32). The firm's Allergen Control program is discussed in the heading, Operations, *Process for the Pistachios Inside the Processing Building*, Allergen Control (on page 44) of this inspection report.
- Where un-roasted products were packaged in the same room as the roasted products are shown in the diagram of the Roaster and Packaging Rooms of this report in the above heading, Operations, *Process for the Pistachios Inside the Processing Building* (on page 39).
- Exhibit #54 & 85 page 2 shows the firm's identified shared equipment and locations where roasted and un-roasted products were processed and packed. Exhibit #85 page 3 shows the locations of the four FDA positive samples collected during this inspection. Exhibit #85 pages 4 and 5 show process flow outlines of the in-shell and kernel in the processing plant.
- Records of running un-roasted product prior to the positive lots and sanitation records (some the firm did not have) are:
 - In Exhibit #86 pages 9-13 is for Roasted Salted pistachios with FMO 2147 W/M packed on 8/6-7/08 and the raw product processed before it is in Exhibit #86 pages 1-8. The closest cleaning record is in Exhibit #86 pages 15-17. The invoice and shipping records are in Exhibit #86 pages 18-19. This FMO 2147 W/M is covered in the FDA 463a Affidavit and FACTS documentary sample can be generated later, if requested. This inspection

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report discusses this FMO 2147 W/M in the heading, *GNC and Sanfilippo Trace backs* (on page 58).

- In Exhibit #19 pages 24-25 is for FMO 2818 C03 LgB-2 packed on 10/7/08. The closest cleaning record is in Exhibit #19 page 27. The pick sheet and shipping records are in Exhibit #19 pages 6-7. Also, DOC 501602 is for in-shell roasted salted pistachios with FMO 2818 C03LgB-2. The two independent laboratory positive *Salmonella* results are in Exhibit #19 pages 9-11.
- In Exhibit #87 is for FMO 2948 W/M 29718 R/S-2018 and FMO 2948 W/M 29728 R/S 2018 packed on 10/23/08. The closest cleaning record is in Exhibit #87 pages 25-27. The invoice and shipping records are in Exhibit #87 pages 20-21 & 23-24. Also, DOC 501604 is for in-shell roasted salted pistachio whole kernels with FMO 2948 W/M 29728 R/S 2018.
- In Exhibit #88 is for FMO 3088 W/M 31128 R/S-2018, 3088 W/M 31218 R/S-2018 and 3088 W/M 31518 R/S-2018 packed on 11/6, 7 & 10/08. The closest cleaning record is in Exhibit #88 pages 49-50. The invoice and shipping records are in Exhibit #88 pages 34-35, 37-38, 42, 43, 47 & 48. Also DOC 501605 is for in-shell roasted salted pistachio kernels with FMO 3088 W/M 31218 R/S 2018.

Cross contamination is anything that is in a food product that should not be there, including potentially harmful microbiological pathogens such as *Salmonella*. Implementing adequate quality control operations and sanitation controls in keeping potential contaminants by raw materials separate from the final food ensures that the foods produced are suitable for consumption. A firm must have planned and systematic procedures in place to adequately detect and eliminate any cross contamination detected.

The firm routinely packaged roasted ready-to-eat pistachios in the same packaging room as their un-roasted pistachios. The roaster room had bin hoppers that un-roasted pistachios were dumped into prior to their roasting, when the roasters were less than (b) (4) away. The firm's employees packaged the roasted pistachios on the same packaging lines as un-roasted pistachios (New Building Transfer hopper), roller-sorter (sizer) and hand sort area (South hand sort). Same employees worked with both un-roasted and roasted pistachios and had access to all areas of the plant. Bins and conveyors to equipment and lines were shared with roasted and un-roasted without any controls in place to verify if they were cleaned/sanitized or if cleaned, adequately cleaned and sanitized. Forklifts, sampling carts and brooms were not dedicated to roasted and un-roasted side.

The firm's sanitation procedures are on page 39 under the heading, Sanitation, of this inspection report.

Discussion with Management:

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Mr. Aguilera said the Red Dye equipment and lines are air blown, swent, water rinsed, scrubbed with a degreaser, water rinsed and sanitized with (b) (4) or (b) (4). The only reference available at the firm describing the cleaning of the Red Dye equipment and lines were the (b) (4) sanitation schedules which stated to clean the *red dye breezeway, clean and sanitize the walls and the floors*, Exhibit #20, page 30.

Mr. Cohen stated that his company is operating now as two independent facilities. One facility is raw and the other facility is roasted. He stated there is no cross traffic for forklifts and all shared equipment has been eliminated which is under a formal SOP that was not available by the close of the inspection.

Mr. Cohen stated national experts have written company SOPs and SSOPs and have reviewed product flow patterns. He stated there is a (b) (4) system for bins. Mr. Cohen stated that conveyor buckets are no longer stored outside and are now dedicated to either the raw or roasted operations. He stated the company's HACCP plan was being rewritten to incorporate new CCPs for the pistachio operations. Mr. Cohen stated the firm is committed to a pathogen free control environment that will detect problems earlier in the process.

SSOPs and SOPs have been developed for proper cleaning before and after product runs, according to Mr. Cohen. He stated there is no longer shared equipment. He stated that a third party is assessing the company's allergen control plan.

OBSERVATION 5

Failure to maintain equipment, containers and utensils used to convey, hold, and store food in a manner that protects against contamination.

Detachable/portable processing conveyor buckets, which had been cleaned, that are used to convey raw and roasted pistachio products were routinely stored outside the covered processing areas and exposed to the outside environment. Also, flexible covers used to protect the buckets did not completely cover the conveyor buckets.

Reference: 21 CFR 110.80(b)(7)

Supporting Evidence and Relevance:

- See Exhibit #59 pages 4 and 5 for the photographs of the exposed conveyor bucket stored in the outside environment.
- Sanitation of the conveyor buckets is discussed in the subtitle, Conveyor Belts and Buckets, (on page 42) of this report.

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Previously cleaned, exposed and un-protected conveyor buckets stored outside to the environment creates the potential for cross contamination when they are placed back into the food processing facility. This was also discussed above in the heading, Operations, *Sanitation*, Conveyor Belts and Buckets (on page 42) of this inspection report, which notes the firm sprays a sanitizer once these conveyor buckets are installed.

Discussion with Management:

Mr. Cohen stated that conveyor buckets are no longer stored outside and they will be stored in their respective facilities (un-roasted or roasted). Cleaned bins will receive clean (b) (4) and be on a (b) (4) system. They are reviewing and rewriting their HACCP plan and new CCPs are being developed. He said they under the new operation, Pathogen Monitoring Program, that pistachios coming in contaminated will be identified early in the process. Their rewritten SOP and SSOP will not longer allow sharing of equipment.

OBSERVATION 6

The design of equipment and utensils fails to preclude the adulteration of food with contaminants.

Specifically, a blackish cloth-like material was wrapped around the braces of the overflow water funnel of the dewatering screen located in the roaster room. This cloth-like material cannot be adequately cleaned or sanitized.

Reference: 21 CFR 110.40(a)

Supporting Evidence and Relevance:

Environmental FACTS sample INV 482178, sub 2 was taken in this area that was positive for *Salmonella*, see FACTS collection report attached.

Cloth-like material that is collecting moisture and that is not adequately cleaned or sanitized creates the potential of contaminates and microorganisms. This observation was discussed on page 36 and the photograph is in Exhibit #59 page 6 of this inspection report.

Discussion with Management:

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Mr. Cohen stated that the referenced structure is gone and has been replaced with (b) (4). We observed that this structure was removed and replaced with another structure that now drains directly into the floor drain. He stated no water will flow directly onto the floor and (b) (4) will go directly into the drains. Thus, there will be no water on the roaster room floor. (b) (4) ppm) will be placed into the drains according to Frank G. Aguilera, Quality Supervisor.

OBSERVATION 7

Failure to operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-contact surfaces, and food-packaging materials.

Specifically, a portable air circulation fan located next to the Bulk line (b) (4) packaging operation had a buildup of accumulated dust and other debris on the fan blades and fan wire guard.

Reference: 21 CFR 110.20(b)(6)

Supporting Evidence and Relevance:

The facility needs to locate and operate fans and other air blowing equipment in a manner that minimizes the potential for contaminating food, food packaging materials and food-contact surfaces.

The fan was a floor standing portable device that was observed next to bulk line (b) (4) in the packaging room where both raw and roasted (ready-to-eat) products were packaged. There was nothing to prevent the fan from being moved and used at bulk line (b) (4) (used to package roasted products) or moved and used at or near bulk line (b) (4) (used to package roasted and un-roasted products).

Discussion with Management:

Mr. Cohen stated that the cleaning of their fans will be added to their cleaning schedule.

He then stated that his company has made a decision from top to bottom to focus on food safety and the new focus in our industry is to promote the best practices and all the industry has this same approach as confirmed by our industry meetings.

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Mr. Cohen stated his company would respond to the issued FDA 483-Inspectional Observations and we told him to send the FDA 483 response letter to San Francisco District Director Barbara J. Cassens, 1431 Harbor Bay Parkway, Alameda, CA 94502.

REFUSALS

The following refusals were encounter during this inspection and these are reported by Investigator Hamaoka.

The firm refused to allow the use of a camera to take photographs, refused to provide their customer complaint file and refused to sign affidavits.

On 3/27/09 during sample collection, Mr. Cohen refused to allow the use of my camera. I explained to him that it was an inspectional tool that I carry it with me on my inspections and it would accurately identify the areas' for each environmental sub taken. Mr. Cohen said he could not let me use my camera because the company policy does not permit it. I informed him he could take their own photographs along with us. (b) (4) Consultant of (b) (4) came up to me and informed me that Mr. Cohen is refusing the use of the camera. I then called my supervisor who informed me to have Mr. Cohen call SAN-DO's Director of Investigations, by that time FDB was taking the photographs.

I was informed by Ms. (b) (6) Mr. Campos and Mr. Aguilera that Mr. Gibbons was in-charge of complaints. On 4/8/09, we discussed the complaints with Mr. Gibbons who acknowledged he was in charge of complaints and the firm had no complaint file for us to review. See the heading above titled, Complaints of this inspectional report for more information (on page 63).

On 4/30/09, the last day of the inspection, Mr. Cohen said there is a complaint file. I informed him that I requested their complaint file, but was informed there was none. He informed us that they have received no illness complaints. I said I would determine which ones were illness/injury complaints. Also, I had FDB Investigator Bloxsom request for the complaint file since Mr. Gibbons talked about an upset husband calling to obtain cash compensation claiming his wife got sick for a couple of days. Investigator Bloxsom asked Mr. Gibbons for the complaint file and was told there was none. Records of complaints were requested on the 414 Attachment to the FDA 482c (Requests for Records) issued to the firm, see 414 Attachment with FDA 482c attached to this inspection report. No complaint file was provided to us during this inspection.

Mr. H. Lee Cohen, Production Manager, Setton International Foods, Inc. Commack, New York, refused to have Mr. Lapietra and Mr. Campos sign the FDA 463a Affidavits stating to us that he was following company policy in not signing affidavits.

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GENERAL DISCUSSION WITH MANAGEMENT

On 4/14/2009, Harris (Lee) L. Cohen, Plant Manager, Setton International Foods, Inc. Commack, New York provided to us a copy of Setton Farms Strategic Plan for a new corporate focus and remediation plan for Setton Pistachio of Terra Bella, Inc. (See Exhibit #89 pages 1-12). He accompanied us through the facility noting where changes had occurred or were going to occur. We were also accompanied by consultant (b) (4)

(b) (4) and (b) (4) and FDB Investigator Bloxsom. Mr. Cohen stated his company had been part of pistachio industry meetings where Good Agriculture Practices were discussed and the major companies in the pistachio industry were unified and would make the necessary changes needed to resolve any food safety issues involving their pistachio products.

Mr. Cohen then walked us through his strategic plan proposals, beginning with the raw pistachio receiving side of the facility. Mr. Cohen stated the initial (b) (4) (b) (4) would be at the (b) (4) at the (b) (4) and at the (b) (4) leading into the covered processing area that would be covered and sealed. He also mentioned another (b) (4) would be applied to the raw pistachio product coming through the conveyor from the silos. The (b) (4) would be redone with (b) (4) and there would be an (b) (4) for every (b) (4) lb. bin and every bin would have (b) (4) identification. All bins would have track back and trace forward traceability. Mr. Cohen stated their HACCP plan would be revised. The raw pistachio operation would be separated from the roasted pistachio processing operation by (b) (4) (b) (4) or (b) (4) common (b) (4). There would be no shared forklifts or employees between the raw and roasted areas. Mr. Cohen stated there might be separate loading docks for the raw and roasted pistachios leaving the facility. He stated the company was going to no longer process diced pistachios and will no longer package pistachios packaged in mesh bags. (b) (4)% of their products will be tested involving (b) (4) sampling steps for *Salmonella*, *Escherichia coli*, *Shigella*, Total Plate Count and Total Coliform. Mr. Cohen stated the airflow pattern would be changed and all drain pipes will go directly into the gutter. New (b) (4) had been placed in the roasters. The dust collecting equipment would be (b) (4) and the packaging room ducts would (b) (4) (b) (4). Mr. Cohen showed us that a new building roof had been installed over the roasters. He stated that a (b) (4) would take place with (b) (4) being placed on containers/bins. Every machine/line would have a (b) (4) to record where every bin or product container had been. He stated an (b) (4) for harvesting would be in place for each load assigned to a specific silo which would equal (b) (4) grower acres of pistachios per silo.

The following eight paragraphs were reported by Investigator Hamaoka. On 4/14/09 after Mr. Cohen and Mr. (b) (4) showed us (FDB Investigator Bloxsom, FDA Investigator Buckalew and I) the (b) (4) coded bins, I asked what their procedures were when they

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receive a positive microbiological test result. Mr. Cohen said the lot would be placed on hold and when they receive a set amount to (b) (4) they will have it (b) (4) (with any others accumulated) once the (b) (4) is validated for pistachios. I told them that they need to also bracket the lots that were produced before and after the positive detect lot and to make sure the related lines are clean since these are all suspect. Mr. (b) (4) said that is not the correct way and that is not a common procedure in the (b) (4). I later brought this up to with firm's management on 4/30/09 when Mr. (b) (4) was not present, which is discussed above in the heading, Objectionable Conditions and Management Response and Discussion with Management (on page 71).

On 4/30/2009, Nicolo (Nick) Lapietra (General Manager) and Lee Cohen again accompanied us (Investigator Buckalew and I) to show what changes had taken place or were scheduled to take place. They pointed out the strip curtains that have been installed at their uniform storage shed. As they walked us through the processing facility they showed us areas where they had food grade paint placed. As Mr. Cohen pointed to the transfer hoppers in the un-roasted side and said these are now only for raw pistachios. Mr. Cohen said they are collecting (b) (4) samples (subs) of (b) (4) grams each (b) (4) for the un-roasted products. He showed us the new (b) (4) for the sample bags that have the (b) (4) and (b) (4) recorded on them. Mr. Cohen mentioned they have new SSOPs for all hoses and the cleaning of them.

They showed us the new walls which were built to separate the raw pistachios from the roasted pistachios and the positive airflow system incorporated in the roasted pistachio processing area. The hoppers (where un-roasted products were dumped to be roasted) that were in the roasting room are now outside the roasting room. (b) (4) and (b) (4) had been installed in the roasters for (b) (4) and record keeping purposes. Mr. Cohen said the roasters were being validated one roaster at a time. The roaster room will have new piping, new (b) (4) of the pitted roaster floor pits and new (b) (4) replacing the former one. Mr. Cohen showed us the new (b) (4) hand sort table that are now located at the end of each of the (b) (4) roasters. Thus, finished roasted product will no longer be transferred by bins to the hand sort rooms located at the un-roasted area.

Mr. Cohen and Mr. Lapietra showed us the packaging room and pointed to the ceiling vents and exposed cooling fans (when the room was a cold storage room) that have been closed off. Mr. Cohen said there is no longer air blowing out from the air lines used to remove the dust and debris on the packaging equipment but now (b) (4) are in the packaging room to (b) (4). He said all the dust collectors that were formerly in the roasting and packaging rooms were moved outside which was verified by us.

All the raw ingredients stored in the Red Dye room had been removed and the firm was in the process of cleaning this room and its related equipment. Mr. Cohen mentioned they

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were considering hiring a third party cleaning firm to clean this packaging room who he mentioned provides COA of their cleaning against certain microorganisms. Otherwise his employees would de-dust, vacuum, clean and sanitize the Red Dye room equipment. He showed a (b) (4) at the (b) (4) of the Red Dye room which will control the employees who enter the processing building. This follows their new SOP of keeping raw and ready-to-eat separate. There will be (b) (4) for the raw side of the processing building. Currently, Mr. Cohen said their warehouse has raw and finished products in one warehouse building but stored separately, yet not separate warehouses. He said they are considering (b) (4) for the raw side.

Mr. Cohen then asked us if our tests show that the *Salmonella* positives were the same species as the isolates they provided. I said that I believed so, but I was not a microbiologist. When I asked, Mr. Cohen said he not received word that these tested by US FDA were the same specie. I told him that he would receive the 704(d) letters for the 4 samples collected at his firm that tested positive since it was requested on the environmental swabs' collections reports. He then requested that their remedial plan be included in the firm's report. We told him that it would be which is in Exhibit #19.

Mr. Cohen said their QA (Quality Assurance) department is no longer reporting to production and now the QA department reports to Setton's senior management. When I asked who senior management was, Mr. Cohen said he was senior management. He said all finished products will be under their (b) (4) procedure and only released with a negative testing result. (b) (4)

(b) (4) He also explained the QC (Quality Control) department and the QA department are not the same. He said the QC department is part of Production and QA is not part of Production. If the test result is positive, (b) (4)

(b) (4) They will (b) (4) (b) (4) process. After these have been through (b) (4) the (b) (4) (b) (4)

Mr. Cohen said the roasted product will be sampled at the rate of (b) (4) gram samples (subs) each for every (b) (4) pounds of product. (b) (4) (b) (4) (b) (4) through their process.

The following subsection was reported by Investigator Buckalew. The management representatives present during the inspection closeout and Form FDA 483 discussion were Nicolo (NMI) Lapietra (General Manager), H. Lee Cohen (Production Manager of Setton International Foods, Inc.), Jeffery J. Gibbons (Plant Manager) (b) (6) (Office Clerk), Octavio (NMI) Campos (Production Supervisor) and Frank G. Aguilera (Quality Supervisor). The FDA 483 Inspectional Observations was issued to Nicolo (NMI) Lapietra (General Manager) in the absence of Mr. Setton. Each FDA 483 item was read and

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discussed with the firm's management. See heading, Objectionable Conditions and Management's Response (on page 64), in this report for management responses regarding the FDA 483 observations.

The following inspectional observations not listed on the Form FDA 483 were discussed with management:

Production records that we reviewed during the inspection noted errors in them which included missing/incorrect dates, missing time, missing FMO/Lots, misidentification of product run, misidentified FMO/Lot numbers, holes were punched through the records which destroyed some information recorded and unexplained lot coding changes. Some of the records were difficult to distinguish a.m. or p.m. for the time recorded. This delayed the FDA gathering of product recall and trace back information. Thus, there were three voluntary recall announcements by the firm with three separate voluntary recall letters issued. Even Ms. (b) (6) had problems with the records of the firm's timeline for the five positive samples they had and had to revise the timeline 4 different times, (Exhibit #50). At the end of the inspection (4/16/09) we discovered that one employee tends to randomly record their months and dates flipped.

Their lot coding system according to Mr. Cohen, Setton International Foods, Inc., is a work in progress and he is working with consultant (b) (4) for lot tracking of (b) (4) lb. lot sizes with (b) (4) which will be monitored for four different types of microbiological pathogens. The (b) (4) will allow trace back and trace forward accountability to the original (b) (4) lbs. of raw pistachios received. Currently, the (b) (4) for the raw bulk products have the following information for: The (b) (4) (b) (4) It is now used in the raw pistachio operations with dump and fill logs for the (b) (4) lb. pistachio and with lots at hand sorting. According to Mr. Cohen, the documentation for this started about (b) (4) days ago. The lot coding system is still in progress for the roasted pistachios and the SOP is not written yet. Mr. Cohen said it will have a track and trace system also.

The (b) (4) sampling results had no direct links to the product being tested was discussed with the firm's management. Compared to the (b) (4) reports, the (b) (4) microbiological laboratory reports did not have any direct link to the lot of pistachios being sampled. In response to this observation, Mr. Cohen, Setton International Foods, Inc., stated that Setton is now using (b) (4) and has a new sampling SOP. So far, according to Mr. Cohen, (b) (4) samples have been taken from the (b) (4) lb. raw pistachio coded lots and the analytical findings for the raw pistachio products sampled have been negative. Mr. Cohen said the (b) (4) and had recently (b) (4) (b) (4) treatment was brought up by Mr. Cohen who talked

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about the validation for in-shell and kernel pistachios being studied by (b) (6)
(b) (4)

The holes and gaps observed on the sides and under of the rollup doors in the warehouse areas (southeast and northeast doors) were pointed out to the firm's management. We noted on 4/30/09 that the firm had installed new doors but gaps on the side of the north east door still existed and were pointed out to Mr. Cohen. In responses to this observation, Mr. Cohen, Setton International Foods, Inc., stated this was a work in progress. The maintenance department, according to Mr. Cohen, has started the process of ordering and placing (b) (4) of the rollup doors to close the gaps so light cannot be seen at the bottom of the doors.

The (b) (4) instrument had no records present to indicate that it had been calibrated. In response to this observation, Mr. Aguilera stated he checked with (b) (4) different (b) (4) instrument suppliers, and has decided to purchase the one manufactured by (b) (4). The calibration, according to Mr. Aguilera, is done at the factory site and can be checked using a blank cartridge. He said there will be a SOP developed to cover the (b) (4) testing procedures. He said two people have been recently trained to use and calibrate it; and more employees will be trained later.

The sanitation records reviewed did not have the sanitizer listed, amount of sanitizer used, or the concentration of the sanitizer. In response to this observation, Mr. Aguilera stated an SOP is being developed to address the sanitation program in regards to sanitizer levels, amounts used, and concentration checks using test strips. He said they are currently recording the date, amount used, test strip's information and now checks each sanitizing solution before it is issued.

Conveyor bucket cleaning practices that were observed, found that employee's gloves and scrubbing pads were left unattended and some had fallen on the ground during a break. When the employees returned, the gloves and scrubbing pads were picked up by employees who continued to clean the conveyor buckets without sanitizing the gloves or scrubbing pads, Exhibit #59 page 8.

The firm's plastic bins that were used to hold and transport raw and roasted pistachios had no sanitation verification that they had been cleaned and sanitized prior to being used for food storage. In response to this observation, Mr. Aguilera stated the bin cleaning procedures have changes and there will be a tracking log for bin cleaning and records are now kept to show when the cleaning and sanitizing was done for each bin. Mr. Cohen said now they will have separate bins for the raw and roasted and will now monitor the bins. The (b) (4) bins will be for roasted pistachios only.

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Footbaths or other sanitizing systems were not present to prevent the movement of pathogens from one area to another area by employees. In response to this observation, Mr. Cohen, Setton International Foods, Inc., stated the pistachio industry is still reviewing the footwear cleaning issue and is awaiting guidance on what to use as a sanitizer. He also said together with (b) (4) other pistachio industry members there were discussions of a (b) (4) (b) (4) or (b) (4) type of footbath in place of a (b) (4). He mentioned since his plant is separating between raw and roasted pistachios now, this may be of less concern.

Women's restrooms at the hand sorting area did not have hot water and was far from the roasting and packaging operations. Mr. Aguilera said some of the ladies complained that it is too hot. In response to this observation, Mr. Cohen, Setton International Foods, Inc., agreed they have grown and stated he will be reviewing restroom protocol and see if there is a need for additional restrooms or hand washing stations.

I warned General Manager Nicolo (NMI) Lapietra and the other management present, pending further US FDA review, that his firm, if corrections were not done, they could be subject to further regulatory/legal actions such as possible product seizure, injunction and/or prosecution actions, if warranted. I discussed the following sections of the Federal Food, Drug, and Cosmetic Act: Sections, 301, 302, 303, 304, 402, & 403. Copies of the Federal Food, Drug, and Cosmetic Act, Chapter III Prohibited Acts and Penalties, 401- Definition of Food, 402-Adulterated Foods and 21 Code of Federal Regulations 110 Current Good Manufacturing Practice in Manufacturing, Packaging or Holding of Human Food were provided to the firm's management for their reference.

ADDITIONAL INFORMATION

Copies of "Protecting the Foods Supply," "Importers and Filers: Food Security Preventive Measures Guidance" and the ALERT card were provided to Mr. Gibbons, Plant Manager. The acronyms of ALERT were reviewed with him. (b) (3) (A)
(b) (3) (A)

SAMPLES COLLECTED

Ten physical samples (with 254 environmental subs collected) were collected at the firm during this inspection that are listed in the spreadsheet below. The firm also collected duplicate environmental samples along with the FDA/FDB inspection team. At the time of this inspection, the firm was not observed collecting duplicate finished product samples for the finished product samples collected by FDA. The first nine INV (investigational) samples were collected and initially analyzed by SAN-DO which were five samples with 254 environmental subs collected and 4 samples of four different lots of finished products. There were four sample numbers that were positive for *Salmonella*:

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- 1) FDA FACTS # INV 482178 sub 2,
- 2) INV 490163 sub 67,
- 3) INV 489158 sub 9 and
- 4) INV 482179 finished product. (The interstate commerce for the finished product was later documented on FACTS DOC 501601).

The 10th sample (FACTS 531954) was an isolate of pistachios from lot (FMO/Lot 2818C03 LgB02) that was analyzed for *Salmonella* by ^{(b) (4)} that tested positive. For INV 531954, see the spreadsheet below and this inspection report's Microbiological heading, The Five Positive *Salmonella* Results that Setton Received and Had Knowledge - 1) FMO/Lot 2818C03 LgB-2 subsection (on page 48) for more information on this lot and isolate.

The following spreadsheet is an outline of the ten physical samples collected during this inspection. The first samples listed were submitted and analyzed by FDA SANDO laboratory. The collection reports are attached to this inspection report.

FACTS Sample #	DATE	SAMPLE	LOT or comment	FDA 483 OBSERVATION	PHOTO/ EXHIBIT	I/S	PRODUCTION DATE	LINKS
501599	3/27/2009	31 environmental subs	Not Applicable			(No Salmonella detected)	Not Applicable	-----
490162	3/27/2009	Finished	(b) (4) MAR 25 2010			(No Salmonella detected)	3/25/2009	-----
489157	3/27/2009	Finished	(b) (4) MAR 26 2010			(No Salmonella detected)	3/26/2009	-----
482178	3/28/2009	59 environmental subs	Sub 2 + for Salmonella by FDA	#6 (this +swab was taken in the area described)	Exhibit #92 pg 1	+ was same <i>Salmonella</i> speice, see DOC samples 501601/6	Not Applicable	+ for <i>Salmonella</i> detected by FDA Lab
490163	3/28/2009	75 environmental subs	Sub 67 + for Salmonella by FDA	#4 (this +swab was taken at the roller sorter equipment)	Exhibit #92 pg 1	+ was same <i>Salmonella</i> speice, see DOC samples 501601/6	Not Applicable	+ for <i>Salmonella</i> detected by FDA Lab

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FACTS Sample #		SAMPLE	LOT or comment	FDA 483 OBSERVATION	PHOTO/ EXHIBIT	I/S	PRODUCTION DATE	LINKS
482179	3/30/2009	Finished	(b) (4) +for Salmonella by FDA	#4 (this product was packaged in the red dye room)	Exhibit #92 pgs 3-5	+ was same Salmonella speice, see DOC samples 501601/6	3/17/2009	+ for Salmonella detected by FDA Lab. IS documented in DOC 501601
529672	3/30/2009	Finished	(b) (4)			(No Salmonella detected)	3/19/2009	-----
489158	3/31/2009	57 environmental subs	Sub 9 of air hose was + for Salmonella by FDA	Similar air hoses were observed in contact with the floor which was discussed with the firm	Exhibit #92 pg 2	+ was same Salmonella speice, see DOC samples 501601/6	Not Applicable	+ for Salmonella detected by FDA Lab
501600	4/2/2009	2 water subs	Not Applicable			(No Salmonella detected)	Not Applicable	-----
531954	4/4/2009	Salmonella Isolate from pistachio	isolate from Setton pistachio w/ref. #(b) (4)	#1 & #4		See FACTS DOC 501602 for IS	10/7/2008	+ Salmonella isolate detected by (b) (4) was initially detected by (b) (4) who discarded their isolate

The tables that follow are the 254 environmental swab areas sampled during this inspection. Photographs to the environmental subs were taken by FDB. Thus, IOM (Investigations Operations Manual) procedures were not performed until after receiving copies of the digital photographs from FDB. FDB's given copy was designated at the original master and working copies were made from FDB's given copy. This original master is Exhibit #90 of this inspection report. Thus, the lead collection report or individual collection reports do not contain the original masters of the photographs taken. Please also note photographs of each sub were not taken and other photographs (i.e., photos related to the FDA 483 items) were taken by FDB that were not of environmental subs. This is also explained in a memorandum, see Attachment R.

The non-numeric entries in the PHOTO column indicate no photographs were taken for these subs. There were other photos were taken that were not environmental sub sites. The photographs are attached to the related samples' collection reports that accompany this inspection report.

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3/27/09 FACTS 501599 9:45 am - 6:30 pm						
Sub #	Time	Est. Area	Description	Micro Tool	Photo	DOWNLOAD PHOTO #
C	9:53	—	Closed hydrasponge control	H	—	—
C	9:56	—	Closed spatula control	S	—	—
C	9:57	—	Closed scoop control	P	—	—
C	9:57	—	Closed spoon control	O	—	—
C	9:58	—	Closed dry swab control	D	—	—
C	9:58	—	Closed DE broth control	D/E	—	—
C	9:59	—	Closed sponge on stick control	SS	—	—
C	10:00	—	Closed glove 7-8 control	glove	—	—
C	10:00	—	Closed glove 8.5 control	glove	—	—
C	10:01	—	Closed bag whirlpak control	whirl	—	—
C	10:03	—	Open hydrasponge control	H	—	—
C	10:06	—	Open spoon control	O	—	—
C	10:07	—	Open DE broth control	D/E	—	—
C	10:09	—	Open whirlpak bag control	whirl	—	—
C	10:11	—	Open sponge on stick control	SS	—	—
C	10:12	—	Open dry swab control	D	—	—
C	10:14	—	Open scoop control	P	—	—
C	10:16	—	Open spatula control	S	—	—
C	10:17	—	Open glove 7-8 control	glove	—	—
C	10:19	—	Open glove 8.5 control	glove	—	—
C	10:23	—	Open glove control of hydrasponge	H	—	—
					(camera format 032809-040309.—.jpeg)	
1	10:28	1' X 1'	(b) (4) feeder tray	H	2	002
2	10:42	1' X 1'	infeed bin dumper floor	SS	6	006
3	10:55	4" X 8"	exit of hopper of infeed bin dumper	SS	3	003
4	10:59	5" X 8"	bucket of bucket elevator	H	1	001
5	11:02	3" X 6"	infeed spout of (b) (4)	H	—	—
C	3:37	—	Open hydrasponge control	H	—	—
C	3:51	—	Open DE broth control	D/E	—	—
C	3:53	—	Open sponge on stick control	SS	—	—
C	3:55	—	Open dry swab control	D	—	—
C	3:57	—	Open spatula control	S	—	—
C	4:00	—	Open spoon control	O	—	—
C	4:01	—	Open scoop control	P	—	—
C	4:04	—	Open glove 8.5 control	glove	—	—
3/27/09 FACTS 501599 Continue						

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3/27/09 FACTS 501599 Continue						
Sub #	Time	Est. Area	Description	Micro Tool	Photo	DOWNLOAD PHOTO #
C	4:05	—	Open glove 7-8 control	glove	—	—
C	4:13	—	open glove from hydrasponge	H	—	—
6	4:15	6" X 3"	NE leg of bin/ hopper	H	4	004
7	4:20	1' X 1'	South side of hopper before (b) (4)	H	5	005
8	4:25	8" X " 2	Bar between over head of (b) (4)	H	7	007
9	4:28	1' X 1'	North leg of (b) (4) dry	H	8	008
10	4:34	4" X 4"	Water drain for (b) (4) dryer	D	9	009
11	4:37	3" X 4"	Electrical wire conduit in front of (b) (4) dry	H	10 & 11	010/011
12	4:40	3" X 1' X 4"	ladder & rail (3 of them) to polisher	H	12	012
13	4:44	3' X 3"	north east side of barrel polisher	H	13	013
14	4:49	1' X 1'	northeast of watering screen	H	14	014
15	4:50	1' X 1'	green shovel on catwalk of polisher	H	15	015
16	4:52	1' X 1'	(b) (4) pipe going into polisher	H	16	016
17	4:53	1' X 1'	inside the polisher	H	16	016
18	5:05	1' X 1'	sides on inside water discharge line from belt	H	17	017
19	5:06	1' X 1'	outside (bottom) of water discharge line (tray)	H	18	018
20	5:11	1' X 1'	inside (top) of hopper feeding into roaster	SS	21	021
21	5:20	1' X 1'	(b) (4) pipes on top of roaster	H	22	022
22	5:33	1' X 1'	inside roaster (b) (4) belt and side	H	—	—
23	5:36	1' X 1'	inside of door on roaster (b) (4) 2nd set of doors (right)	H	25	025
24	5:44	1' X 1'	motor to the sock from the packaging	H	26	026
25	5:51	1' X 1'	underneath roaster (b) (4)	H	—	—
26	5:52	1' X 1'	junction on floor under roaster (b) (4)	H	29	029
27	5:54	3" X 8"	bottom of cooling belt 2nd door	H	30	030
28	5:58	3/4" X 5"	hole & floor juncture crack (by leg of (b) (4)	D	32	032
29	6:04	4" X 12"	inside discharge tank	H	33	033
30	6:08	5" X 12"	pitted floor between roaster Eastside	H	34	034
31	6:12	3" X 6"	air shoot in kernel meat side	H	35	035
C	6:14	—	Open hydrasponge control	H	—	—
C	I	—	Open DE broth control	D/E	—	—
C	I	—	Open sponge on stick control	SS	—	—
C	▼	—	Open dry swab control	D	—	—
C	6:28	—	open glove from hydrasponge	H	—	—

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Sub #	Time	Est. Area	Description	Micro Tool	Photo	DOWNLOAD PHOTO #
3/28/09 FACTS 482178 9:15 am to 5:00 pm						
C	9:27	—	Open control for glove control 8.5 size	glove	—	—
C	9:22	—	Open control for hydrasponge	H	—	—
C	9:22	—	Open control for Sponge on a stick	SS	—	—
C	9:22	—	Open control for D/E Broth	D/E	—	—
C	9:22	—	Open control for Dry Swab	D	—	—
C	9:22	—	Open control for Whirl-Pak	whirl	—	—
C	9:28	—	Open control for glove from hydrasponge packet	H	—	—
				Camera Format		032809-040309.--.jpg
1	9:41	1' X 1'	SW wall of Roaster Room	H	36	036
2	9:44	1' X 1'	Overflow water funnel from dewatering screen (Commercial)	H	37	037
3	9:48	1' X 1'	South wall (East of (b) (4) mixing tanks) rusted part at bottom	H	38	038
4	9:50	1' X 1'	Back of (b) (4) feed (b) (4) buckets	H	39	039
5	9:54	1' X 1'	Green belting on (b) (4)	H	40	040
6	9:57	1' X 1'	Eye wash area on south wall	H	41	041
7	10:01	1' X 1'	Top of bin dumper control box	H	42	042
8	10:05	1' X 1'	Floor area next to man door & south of wall (west of (b) (4) tanks)	H	43	043
9	10:07	1' X 1'	Crack on floor between (b) (4) (b) (4) and (b) (4) tanks	D	44	044
10	10:11	1' X 1'	Air inlet pipe to polisher	H	45 & 46	045/046
11	10:14	1' X 1'	Drip drain line (end)	H	47 & 48	047/048
12	10:16	1' X 1'	Drip drain line (top)	H	49	049
13	10:22	2" X 4"	SW leg of polisher support (bolt holes)	D	50	050
14	10:25	1' X 1'	Bottom N of polisher catwalk	H	51 & 52	051/052
15	10:29	1' X 1'	Back of conveyor belt and inside of drip tray	H	53	053
16	10:32	1' X 1'	(b) (4) polisher catwalk ladder (north side)	H	54	054
17	10:37	1' X 1'	Bottom of polisher catwalk south side	H	55	055
18	10:42	1' X 1'	South side roaster bed hopper	H	61	061
19	10:48	1' X 1'	Floor drain south end	H	62 & 63	062/063
20	10:50	1' X 1'	Back of shovel hanging on south wall	H	64	064
C	1:31	—	Open control for Dry Swab	D	—	—

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Sub #	Time	Est. Area	Description	Micro Tool	Photo	DOWNLOAD PHOTO #
C	1:32	—	Open control for hydrasponge	H	—	—
C	1:33	—	Open control for glove from hydrasponge packet	H	—	—
C	1:34	—	Open control for Sponge on a stick	SS	—	—
C	1:34	—	Open control for D/E Broth	D/E	—	—
C	1:35	—	Open control for Whirl-Pak bag	whirl	—	—
C	1:35	—	Open control for sterile glove 8.5	glove	—	—
21	1:47	1' X 1'	South wall broom head (used to sweep up spills)	H	—	—
22	1:52	1' X 1'	South side panel of feed hopper	H	—	—
23	2:01	2" X 2"	NW of roasting room's internal & external adapter of air hose	D	—	—
24	2:05	1' X 1'	South side frame structure at underside	H	—	—
25	2:09	1' X 1'	Top and back panel inside (b) (4) dryer	H	—	—
26	2:15	1' X 1'	Southside (b) (4) internal door panel	H	—	—
27	2:20	1' X 1'	(b) (4) air deflector on (b) (4) dryer	H	—	—
28	2:24	1' X 1'	(b) (4) top of engine block end of	H	—	—
29	2:31	1' X 1'	(b) (4) door of cooling zone	H	—	—
30	2:35	1' X 1'	(b) (4) door air deflector	H	—	—
31	2:42	1' X 1'	(b) (4) door top cooling panel	H	—	—
32	2:46	1' X 1'	(b) (4) door of (b) (4) air deflector bottom middle panel	H	—	—
33	2:49	1' X 1'	(b) (4) door of (b) (4) it deflector bottom outer panel	H	—	—
34	2:52	1' X 1'	(b) (4) door of (b) (4) panel guard	H	—	—
35	2:58	1' X 1'	(b) (4) door of (b) (4) air deflector panel	H	—	—
36	3:03	1' X 1'	(b) (4) cooling zone door (b) (4) bottom panel	H	—	—
37	3:05	1' X 1'	(b) (4) cooling zone door (b) (4) middle panel underside of conveyor belt	H	—	—
38	3:12	1' X 1'	(b) (4) cooling zone door (b) (4) cross bar at end of cooling zone	H	—	—
39	3:14	1' X 1'	(b) (4) cooling zone door (b) (4) cross bar after cooling zone	H	—	—
C	3:16	—	Open Control for Scoop	—	—	—
40	3:20	200 g	About 200g of air dust collected in air (b) (4) filter	Scoop	—	—
41	3:29	1' X 1'	End of cooling zone right panel	H	61	DSCN2726
42	3:32	1' X 1'	End of cooling zone flap panel	H	62	DSCN2727

Establishment Inspection Report

Setton Pistachio of Terra Bella, Inc.

Terra Bella, CA 93270

FEI:

2939582

EI Start:

03/26/2009

EI End:

04/30/2009

3/28/09 FACTS 482178 Continue						
Sub #	Time	Est. Area	Description	Micro Tool	Photo	DOWNLOAD PHOTO #
43	3:37	1' X 1'	Top of end of cooling zone	H	63	DSCN2728
44	3:42	6" X 6"	Northeast end of the (b) (4) roaster	H	64	DSCN2729
45	3:44	4" X 18"	Floor juncture at East end of (b) (4) roaster	H	65	DSCN2730
46	3:47	1' X 1'	Floor to man door leading to outside at eastside of roaster	H	66	DSCN2731
47	3:50	1' X 1'	Front of East end garage door	H	67	DSCN2732
48	3:53	—	North end air hose fitting	H	68	DSCN2733
49	4:11	1' X 1'	Bottom tray of initial hopper	H	—	—
50	4:17	1' X 2'	(b) (4) step rail in Southside sorting room	H	69	DSCN2734
51	4:22	1' X 1'	(b) (4) roller in sorting room, insect tray	H	70	DSCN2735
52	4:26	1' X 1'	(b) (4) roller in sorting room, hand sort shoots	H	71	DSCN2736
53	4:31	1' X 1'	(b) (4) roller in sorting room, bottom of hopper (internal surface)	H	72	DSCN2737
54	4:33	1' X 1'	(b) (4) roller in sorting room, conveyor belt	H	73	DSCN2738
55	4:34	1' X 1'	(b) (4) roller in sorting room, top rail above florescent light	H	74	DSCN2739
56	4:35	1' X 1'	Wall in sorting room, south side	H	75	DSCN2740
57	4:39	1' X 1'	Bottom of metal footing plus concrete surface	H	76	DSCN2741
58	4:42	1' X 1'	(b) (4) roller out side sorting room, guard panel	H	77	DSCN2742
59	4:46	1' X 1'	(b) (4) roller out side sorting room, motor shield	H	78	not on reader
C	4:51	—	Open control on open whirl pack bag	—	—	—
C	4:52	—	Open control on scoop	—	—	—
C	4:53	—	Open control on hydrasponge	—	—	—
C	4:54	—	Open control on Sponge on Stick	—	—	—
C	4:55	—	Open control on D/E Broth	—	—	—
C	4:56	—	Open control on glove from hydrasponge	—	—	—
3/28/09 FACTS 490163 10:15 am to 5:30 pm						
C	10:31	—	Open control for gloves, Size 6.5	glove	—	—
C	10:36	—	Open control sponge on a stick	SS	—	—
C	10:37	—	Open control for glove with Hydra Sponge packet	H	—	—
C	10:38	—	Open control for Hydra Sponge	H	—	—
C	10:40	—	Open control for wet swab	W	—	—
C	10:40	—	Open control for DE broth	DE	—	—

Establishment Inspection Report
 Setton Pistachio of Terra Bella, Inc.
 Terra Bella, CA 93270

FEI: 2939582
 EI Start: 03/26/2009
 EI End: 04/30/2009

3/28/09 FACTS 490163 Continue						
Sub #	Time	Est. Area	Description	Micro Tool	Photo	DOWNLOAD PHOTO #
CC	10:41	—	FisherBrand Latex Powder Free Sterile Surgical Gloves, Size 6.5	glove	—	—
CC	10:41	—	Bel-Art Products Sterilware Red Scoop	P	—	—
CC	10:42	—	Hydra Sponge blue glove	H	—	—
CC	10:42	—	10 ml D/E Neutralizing broth with swab	W	—	—
CC	10:43	—	10 ml D/E Neutralizing broth with flip top	DE	—	—
1	10:52	1' x 1'	Inside bucket conveyer above 25 lb bulk package	H	—	—
2	10:53	1' x 1'	Outside bucket conveyer above 25 lb bulk package	H	—	—
3	10:55	3" x 1'	Ducting over bulk hopper	SS	—	—
4	10:56	1' x 1'	Ducting area coming into South end of packaging line	H	—	—
5	11:03	2" x 18"	West railing of bucket conveyor over bulk hopper	SS	—	—
6	11:06	3" x 12"	Above ^{(b) (4)} electrical outlet bulk line platform	H	—	—
7	11:08	5" x 6"	Bottom spout of East hopper of bulk line platform	H	—	—
8	11:11	3" x 6"	Duck piping end on West hopper of bulk line platform	H	—	—
9	11:12	1' x 1'	Of Strip Curtain on bulk line platform	H	—	—
10	11:23	5" x 12"	Of inner Hopper of bulk line platform	H	—	—
11	11:25	1' x 1'	Fan grill on S.E. corner of pkg room	H	—	—
12	11:26	4" x 8"	Panel to scale (weight) of bulk line ^{(b) (4)}	H	—	—
13	11:27	1' x 1'	West dumper floor of bulk line ^{(b) (4)}	H	—	—
OC	1:30	—	Bel-Art Products Sterilware Red Scoop	P	—	—
CC	1:35	—	Bel-Art Products Sterilware Red Scoop	P	—	—
OC	1:36	—	FisherBrand Latex Powder Free Sterile Surgical Gloves, Size 7.0	glove	—	—
OC	1:37	—	10 ml D/E Neutralizing broth with flip top	DE	—	—
OC	1:39	—	Hydra Sponge blue glove	H	—	—
OC	1:37	—	10 ml D/E Neutralizing broth with swab	W	—	—
OC	1:38	—	Hydra Sponge	H	—	—
OC	1:38	—	Sponge on a stick	SS	—	—
OC	1:46	—	Whirl pack	whirl	—	—

Establishment Inspection Report
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 Terra Bella, CA 93270

FEI: **2939582**
 EI Start: 03/26/2009
 EI End: 04/30/2009

3/28/09 FACTS 490163 Continue						
Sub #	Time	Est. Area	Description	Micro Tool	Photo	DOWNLOAD PHOTO #
					Camera format:	032809-040309---.jpg
14	1:54	1' x 1'	Dust chute (b) (4) of bulk line (b) (4)	H	65	065
15	1:56	~200g	Sweepings from shoot (b) (4) of bulk line (b) (4)	Scoop	66	066
16	1:59	1/2 cm	Air hose on East/South side	W	67	067
17	2:03	6" x 6"	Broom near bulk line (b) (4) next to airhose	H	68	068
18	2:04	~200g	Sweepings from (b) (4)	Scoop	69	069
19	2:06	1" x 1"	Vibrator tray of feed hopper of (b) (4)	H	70	070
20	2:10	3" x 5"	Bag filler of (b) (4)	H	71	071
21	2:13	3" x 12"	South edge of packaging conveyer of (b) (4)	H	72	072
22	2:15	1" x 1"	On/Off panel of (main power shut off) of (b) (4)	W	73	073
23	2:18	1" x 1"	Roller conveyer of (b) (4)	H	74	074
24	2:19	1" x 1"	Trash can dolly	H	75	075
25	2:20	1/2 cm	Air hose close to Line (b) (4) printer	W	--	--
26	2:22	6" x 6"	Label machine of (b) (4)	H	--	--
27	2:23	1"	North floor pit next to (b) (4) pkg line	W	--	--
28	2:26	1' x 1'	Gear Assembly of bagger line (b) (4)	H	76/77	076/077
29	2:31	1' x 1'	South side of hopper to (b) (4) pkg equip	H	79/80/81	079/080/081
30	2:33	1' x 1'	East side of hopper to (b) (4) pkg equip	H	79/80/81	079/080/081
31	2:35	1' x 1'	Motor on top of South side of hopper (b) (4) pkg equip	H	79/80/81	079/080/081
32	2:36	1' x 1'	Inside of hopper to (b) (4) pkg equip (inside front wall)	H	79/80/81	079/080/081
33	2:38	1' x 1'	Inside of hopper to (b) (4) pkg equip (inside right side)	H	79/80/81	079/080/081
34	2:44	1' x 1'	Product cone feed for (b) (4) packager	H		
35	2:45	4" x 4"	Fan grill looking over labeling area	W		
36	2:47	5" x 6"	Top of dust (b) (4) on top of (b) (4) packager	H		
37	2:49	4" x 4"	Plastic dust diverter on top of (b) (4) packager	W		
38	2:50	6" x 6"	Moisture trapper bottle East hopper Bulk Line (b) (4)	H	82	082

Establishment Inspection Report

Setton Pistachio of Terra Bella, Inc.

Terra Bella, CA 93270

FEI:

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EI Start:

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EI End:

04/30/2009

3/28/09 FACTS 490163 Continue						
Sub #	Time	Est. Area	Description	Micro Tool	Photo	DOWNLOAD PHOTO #
39	2:55	10" x 10"	Shoot of westside hopper	H	83	083
40	2:59	1' x 1'	Pass through hole of bucket conveyer (the flat surface)	H	84	084
41	3:10	6" x 1'	Conveyer bucket (side feed conveyer)	H		
42	3:14	6" x 6"	Safety screen on side feed conveyer	H	85	085
43	3:18	6" x 6"	Box off chute on the box off hopper	H	88	088
44	3:19	15" x 15"	Chute from the (b) (4) unit – inside	H	89	089
45	3:22	6" x 6"	Chute from the (b) (4) unit – outside	H	89	089
46	3:24	5" x 10"	Nut rake (rake for nuts)	H	90/91	090/091
47	3:42	1' x 1'	South East swamp cooler vent beam(ceiling) - samplers on manlift	H	98/99	098/099
48	3:43	5" x 6"	Fire sprinkler pipe adjacent to South East swamp cooler vent beam	H	99	099
49	3:47	1' x 1'	South West swamp cooler (ceiling)	H	100/101	100/101
50	3:55	1' x 1'	Bulk line scale chute West	H	102	102
51	3:56	1" x 6"	Floor seam directly below bulk line scale shoot West	W	—	—
52	3:58	3" x 10"	Back jaw Of (b) (4) Bulk Line (b) (4)	H	103	103
53	4:00	6" x 12"	Screen section North West (b) (4)	H	—	—
54	4:22	6" X 6"	Inside rim of bin dumper raw line	H	104	104
55	4:24	6" x 6"	Bottom of bin dumper, raw line, inside bar	H	104/105	104/105
56	4:31	18" x 3"	Back left plate for leg of bin dumper, raw line	H	105	105
57	4:33	6" x 6"	Instrument panel of bin dumper, raw line	H	105	105
58	4:34	6" x 6"	Chute (b) (4) or raw	H	106	106
59	4:36	6" x 6"	Right side framework for bin dumper, raw line	H	105	105
60	4:42	1" x 6"	Crack in floor in center of sheller room	W	107	107
61	4:43	1" x 6"	Crack in floor in center of sheller room, adjacent to	W	107	107
62	4:47	6" x 6"	Roller sizer platform, feed hopper, top of chute	H	108	108
63	4:49	3" x 6"	(b) (4) motor on roller sizer platform	H	108	108
64	4:50	1' x 6"	Top rail Roller sizer platform railing	H	108	108
65	4:51	1/2" x 6"	Chain bucket on (b) (4) roller sizer platform	H	108	108
66	4:54	6" x 6"	Roller sizer discharge below (b) (4) roller sizer platform	H	108	108
67	4:55	6" x 6"	Roller sizer discharge, slo (b) (4)	H	108	108

Establishment Inspection Report

Setton Pistachio of Terra Bella, Inc.

Terra Bella, CA 93270

FEI: **2939582**

EI Start: 03/26/2009

EI End: 04/30/2009

3/28/09 FACTS 490163 Continue						
Sub #	Time	Est. Area	Description	Micro Tool	Photo	DOWNLOAD PHOTO #
68	5:09	1/2" x 1/2"	Floor, small pit where raw line was in New Bldg (SW leg)	W	109	109
69	5:12	1/2" x 1/2'	Floor seam in front of raw line	W	109	109
70	5:15	1/2" x 1/2'	Exit door bottom left door frame in East door in New Bldg	H	—	—
71	5:16	1/2" x 1/2'	Airline hose in New Bldg, East wall	H	110	110
72	5:18	1/2" x 1/2'	Broom next to exit door, New Bldg	H	111	111
73	5:19	3" x 10"	Top of wall beam on N. East end in New Bldg	H	111	111
74	5:20	1/2" x 1/2"	Pit/ hole in floor SW corner of Raw line hopper (used to be)	H	—	—
75	5:21	1' x 1'	North New Bldg, North East Roll up door (blue), lower left side	H	112/113	112/113
3/31/09 FACTS 489158 9:15 am to 3:45 pm						
CC	920	—	Sponge- stick dry	SS	—	—
CC	↓	—	Gloves Size 7.0	glove	—	—
CC		—	Hydrasponge with D/E Broth	H	—	—
CC		—	10mL D/E broth with Swab	W	—	—
CC		—	10mL D/E broth	D/E	—	—
CC		—	WhirlPak Bag	whirl	—	—
CC		930	—	Scoop	P	—
OC	↓	—	Sponge- stick dry	SS	—	—
OC		—	Gloves Size 7.0	glove	—	—
OC		—	Hydrasponge	H	—	—
OC		—	Hydrasponge glove	H	—	—
OC		—	D/E broth with swab	W	—	—
OC		—	D/E broth	D/E	—	—
OC		—	WhirlPak Bag	whirl	—	—
OC		—	Scoop	P	—	—
				Camera format series	-- .jpg	
1	948	6 X 6	leg of hopper next to (b) (4)	H	755	001
2	952	4 X 3	leg of stand under hopper shoot next to (b) (4)	H	756	002
3	956	4 X 4	belt under buckets of (b) (4)	H	757	003

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 Terra Bella, CA 93270

FEI: 2939582
 EI Start: 03/26/2009
 EI End: 04/30/2009

3/31/09 FACTS 489158 Continue						
Sub #	Time	Est. Area	Description	Micro Tool	Photo	DOWNLOAD PHOTO #
4	957	2 X 2	wheel of drum dolly next to (b) (4)	Q	758	004
5	1000	6 X 6	side wall of catch bin under sorter	H	759	005
6	1001	1 X 1	bolt- under catch shoot of sorter	Q	760	006
7	1002	8 X 8	Screen under catch shoot of sorter	H	761	007
8	1004	1 X 1	hole in cement under sorter	Q	762	008
9	1011	6 X 1	Airline hose under top sizer catwalk	H	763	009
10	1016	1 X 6	Sizer slo (b) (4) plate belt	H	764	010
11	1019	2 X 7	bolt for xLg- Lg sizer	H	766	011
12	1028	6 X 6	Jumbo shoot cover (North)	H	767	012
13	1029	6 X 4	side door (east) of sizer	H	768	013
14	1034	4 X 4	21/25 eye feed (b) (4) bucket	H	769	014
15	1036	10 X 10	(b) (4) blower guard	H	770	015
16	1038	2 X 8	(b) (4) airline	H	771	016
17	1041	6 X 6	(b) (4) reject leg hopper	H	772	017
18	1043	4 X 4	Bucket next to reject leg hopper (b) (4) reject)	H	773	018
19	1104	3 X 8	Lower belt side feed conveyor	H	774	019
20	1104	6 X 4	Roller for side feed conveyor	H	775	020
21	1108	1 X 12"	Rail (b) (4) for side feeder	H	776	021
22	1109	1 X 1	Under bucket for side feeder	H	777	022
23	1110	12 X 12	ceiling near vent above side feeder belt (insulation)	H	778	023
24	1113	1 X 12"	Electric line under vent (ceiling near side feeder)	H	779	024
25	1114	12 X 12	Top of ceiling light near vent	H	780	025
26	1122	12 X 12	(b) (4) air leg	H	781	026
27	1123	12 X 12	Fan next to (b) (4)	H	782-783	027/028
28	1125	12 X 12	White shovel next to needle picker	H	784	029
29	1127	12 X 12	green shovel next to needle picker	H	785	030
30	1130	12 X 4	broom next to green shovel near needle picker	H	786	031
31	1131	1 X 1	Air hose next to 18/20 needle picker	Q	787	032
32	1134	4 X 4	ladder on floor sweeps control bin next to (b) (4)	H	788	033

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3/31/09 FACTS 489158 Continue						
Sub #	Time	Est. Area	Description	Micro Tool	Photo	DOWNLOAD PHOTO #
33	1136	6 X 6	Lg Non-split (N/S) shoot	H	789	034
34	1138	4 X 4	18/20 needle picker (inside)	H	790	035
35	1144	6 X 6	Inside of 21/35 needle picker	H	791	036
36	1147	2 X 8	Air hose hanging on wall across from 18/20 needle picker	H	792	037
—	—	—	<u>Open Controls</u>		—	—
OC	1149	—	Hydrasponge	H	—	—
OC	1149	—	Hydrasponge glove	H	—	—
OC	1149	—	size 7	glove	—	—
OC	1150	—	Whirlpak	whirl	—	—
OC	1154	—	D/E Broth & Swab	W	—	—
OC	1345	—	<u>Open Controls Old Hand Sorting Room</u>	—	—	—
OC	↓	—	Hydrasponge	H	—	—
OC	↓	—	Hydrasponge glove	H	—	—
OC	↓	—	Whirlpak	whirl	—	—
OC	↓	—	D/E Broth & Swab	W	—	—
CC	↓	—	<u>Closed Controls</u>	—	—	—
CC	↓	—	Hydrasponge & glove	H	—	—
CC	↓	—	Whirlpak	whirl	—	—
CC	↓	—	D/E Broth & Swab	W	—	—
37	1353	4 X 4	Sorting table ^{(b) (4)}	H	793	038
38	1355	12 X 12	Fan on back wall of old sorting room	H	794	039
39	1357	1 X 4	Trashcan dolly wheel	H	795	040
40	1359	15 X 15	Blue shovel	H	796	041
41	1401	2 X 8	Sweeper broom with light blue and gray bristles	H	797	042
42	1404	3 X 3	Face mask	Q	798	043
43	1406	4 X 8	Feeder switch from table ^{(b) (4)}	H	799	044
44	1408	1 X 48	Bolt and side rails from table ^{(b) (4)}	H	800	045
45	1409	8 X 12	Reject shoot for table ^{(b) (4)} closest to hopper next to needle picker	H	801	046

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FEI: 2939582
 EI Start: 03/26/2009
 EI End: 04/30/2009

3/31/09 FACTS 489158 Continue						
Sub #	Time	Est. Area	Description	Micro Tool	Photo	DOWNLOAD PHOTO #
OC	1417	—	Open Controls	—	—	—
OC	↓	—	Scoop	P	—	—
OC	↓	—	Blue gloves from hydrasponge pack	H	—	—
46	1421	36 X 36	Dust particles on floor next to needle picker that fell from open ceiling vent; removed to be replaced	S	802	047
		—	Open Controls (in finishing room extension)	—	—	—
OC	1426	—	Hydrasponge	H	—	—
OC	1426	—	Hydrasponge glove	H	—	—
OC	1426	—	Whirlpak bag	whirl	—	—
47	1432	4 X 10	Finishing room extension, Row (b) (4) junction under roof leak area	H	803	048
48	1433	3 X 10	Crack on floor near end of Row (b) (4) before junction	H	804	049
49	1435	6 X 12	Support beam b/t Row (b) (4)	H	805	050
50	1437	12 X 12	Roof leak seam, row (b) (4)	H	806	051
51	1445	5 X 18	Seam of beam @ room junction, row (b) (4)	H	807	052
52	1447	6 X 12	Exposed area of wall junction walkway next to row (b) (4)	H	808	053
OC	1506	—	Open Controls (outside Red Dye Bldg near (b) (4)	—	—	—
OC	↓	—	Whirlpak bag	whirl	—	—
OC	↓	—	Hydrasponge	H	—	—
OC	↓	—	Hydrasponge glove	H	—	—
53	1512	4 X 6	Rain spout/drain outside Red dye room/ near shed	H	809	054
54	1514	9 X 24	Tire, left front, forklift # (b) (4)	H	810	055
55	1515	9 X 25	Tire, right front, forklift # (b) (4)	H	811	056
56	1517	2 X 12	Forklift mask, forklift # (b) (4)	H	812	057
57	1519	4 X 6	Rain spout/ drain near (b) (4)	H	813	058
OC	1534	—	Hydrasponge	H	—	—
OC	1534	—	Hydrasponge glove	H	—	—

KEY TO THE ABBREVIATIONS FOR CONTROLS & MICRO TOOL	
C	Control
CC	Closed Control otherwise written
OC	Open Control otherwise written
D	Dry Swab
D/E	DE broth
H	Hydrasponge
O	spoon otherwise noted
P	scoop otherwise noted
S	Spatula
SS	Sponge on a Stick
W or Q	Wet Swab
whirl	Whirl pak bags

No in-line samples were collected since the firm was not packaging during this inspection. The firm sorted and ran product at the (b) (4) roaster on 3/27/09 for the roaster's validation that was performed by (b) (4) (b) (4)

All of the firm's undercover (b) (4) sq. ft. processing and storage areas were not environmentally swabbed for *Salmonella*. The sampling was performed with two sampling teams. One team began with environmental sampling at the roasting room and the other team collected finished products. The next day one team took environmentals at the packaging areas and the other team took environmentals at the (b) (4) roaster and its related areas. After the weekend, two more finished products were sampled before ending environmental sampling at the un-roasted incoming processing area. All of the other packaging equipment (b) (4) were not swabbed since these packaging equipments had a common overhead line. Thus, one of the package equipment with the common overhead, the common overflow and common (b) (4) hopper was swabbed. Other packaging equipment and their areas (b) (4) Bulk Line (b) (4) Roller-Sorter (sizer), South Sort Room, and New Building Transfer Hopper) that did not directly share this overhead line were sampled. A finished product from the red dye packaging equipment was sampled in lieu of environmentally sampling the Red Dye packaging equipment. About 224 environmental swabs were collected on 3/27-28 & 31/09 and 4 finished product samples were collected on 3/27/09 and 3/30/09. The firm also collected duplicate subs of samples during FDA's sampling.

The firm's management informed us that they had (b) (4) take environmental subs prior to our sampling and these were all negative (Exhibit #34 &35). The firm also sampled 14 finished products during our inspection and 4 of their samples collected were positive for *Salmonella*. The isolates to 3 of these were forward to FDA

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Kansas City Laboratory. See the heading titled, Microbiological, subsection, Four Positive Finished Products Sampled by the Firm After Initiation of the Inspection, of this inspection report for more information, on page 59).

The following is a description to the 10 documentary samples collected to establish interstate shipments from and to the inspected firm.

FACTS Sample #	DATE	SAMPLE	LOT or comment	FDA 483 OBSERVATION/ EXHIBIT #	LAB W/POSITIVE RESULT	I/S	PRODUCTION DATE	LINKS
501601	4/30/2009	Roasted Salted Garlic/onion flavored pistachios (DOC to INV 482178)	0618D13Lg-1 07629G/O 2007* Related to FACTS sample #482178	Exhibit #9 pgs 3-5	FDA LAB SAN-DO	IS of Ingredient of ingr. That was rec'd from (b) (4)	3/17/2009	DOC sample documenting the interstate movement of an ingredient in the seasoning ingredient of the Garlic/Onion flavored pistachios FACTS smpl #482178
501602	4/30/2009	In shell Roasted/Salted Pistachios	2818 C03 LgB-2* Isolate from (b) (4) on FACTS 531954	#1 & 4	2 private labs: (b) (4)	Shipped to: Planters (b) (4) on 10/14/08 B/L order # (b) (4) (isolate link)	10/7/2008	+ Salmonella by 2 private labs. (b) (4) isolate & (b) (4) isolate
501603	4/30/2009	Roasted/Salted whole pistachio kernels	0578 W/M*	#1	(b) (4)	Shipped to: Kraft Planters/Suffolk (b) (4) on 3/12/09 B/L (b) (4) (isolate link)	on or about 3/6/09	+ Salmonella by private lab (b) (4) Lab ID (b) (4) isolate

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FACTS Sample #	DATE	SAMPLE	LOT or comment	FDA 483 OBSERVATION	Test Info	I/S	PRODUCTION DATE	LINKS
501604	4/30/2009	Roasted/Salted whole pistachio kernels	2948 W/M 29728 R/S- 2018+ for Salmonella by FDA	#4	Kraft/ (b)(4) private hired lab	Shipped to: (b)(4) (b)(4) on 10-31-08 & 11-12-08	10/23/2008	IS (Interstate shipment) documented. This lot is a lot that tested + (private lab) for Salmonella in a Kraft (b)(4) product that contained Setton Pistachios.
501605	4/30/2009	Roasted/Salted whole pistachio kernels	3088 W/M 31218 R/S- 2018 + for Salmonella by FDA	#4	Kraft/ (b)(4) private hired lab	Shipped to: (b)(4) (b)(4) on ~12/11/08 & (b)(4) (b)(4) (b)(4) on 12/3/08	11/7/2008	This is the same lot that tested + (private lab) for Salmonella in a Kraft (b)(4) product that contained Setton Pistachios
501606	4/30/2009	Raw Pistachio Kernels	2407 W/M 28718R- 2014**		County health dept?/later FDA	Shipped to: John B Sanfilippo, Elgin, IL on 10/14/2008 & (b)(4) (b)(4) on 11/03/08	10/13/2008	Relates to FACTS NEW Compl# 81839, FACTS smpl #489709. Lot is one of the lots linked to Connecticut case Xbal pattern to S. Montevideo CT 02033774 matches JIXX01.0011, Target Archer Farms mixed nuts.
501607	4/30/2009	Raw Pistachio Kernels	2507 W/M 25828R- 2014		County health dept?/later FDA	Shipped to: John B Sanfilippo, Elgin, IL on ~9/17/08	9/13-14/08	Relates to FACTS NEW Compl# 81839, FACTS smpl #489709. Lot is one of the lots linked to Connecticut case Xbal pattern to S. Montevideo CT 02033774 matches JIXX01.0011, Target Archer Farms mixed nuts.

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FACTS Sample #	DATE	SAMPLE	LOT or comment	FDA 483 OBSERVATION	Test info	I/S	PRODUCTION DATE	LINKS
501608	4/30/2009	In shell Roasted/Salted Pistachios	0588*	#1	(b) (4)	Costco (b) (4) on 3/18/09	3/13,16-18/09	Lot was tested + Salmonella by (b) (4) Lab ID (b) (4) IS documented on FACTS sample #501608
538400	4/30/2009	Raw field harvested Pistachios	Documenting IS of (b) (4) Pistachios comingled with California pistachios		(b) (4)	Pistachios rec'd from: (b) (4) on 10/8/08	many production dates, firm has no way of tracking, co-mingled with CA pistachios	To document IS to FMO 0418 & 0548 + for Salmonella & on hold at Setton. Respective Lab ID (b) (4) isolates
538401	4/30/2009	Oil Stock By-product	none		not tested	Shipped to: (b) (4) 9/3&4/08	Numerous production dates, not tracked by the firm	

*tested positive by the firm's private laboratory

**2-year old Connecticut male Target's Archer Farms/FACTS complaint #81839

The following FMOs/Lots of pistachios were documented on the unsigned affidavits and documentary sample can be generated if later needed: 2147 W/M, 3088 W/M 31128 R/S-2018, 3088 31518 R/LS-2018 and 3478 B14 LgB2R.

RECONCILIATION EXAMINATION

On 4/3/2009, I, Larkin R. Buckalew, examined a (b) (4) fiber container of raw in-shell pistachios, weight (b) (4) lbs. (See #93 page 2 for a photograph of a similar container) and a (b) (4) tote bag of in-shell pistachios, weight (b) (4) lbs (See Exhibit #93 pages 4 & 5 for a photograph of a similar tote bag). The fiber container and the tote bag with the raw in-shell pistachios inside were intact and no product tampering was evident.

VOLUNTARY CORRECTIONS

Voluntary corrections made by the firm that we verified included:

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- segregating the raw and roasted pistachios operations by rebuilding walls, eliminating false walls and sealing doorways
- installing a new multilayer roof in the roaster room and replacing its overhead ducting system
- thorough manual cleaning (scrubbing) of the roasters
- installing (b) (4) to the roasters
- removing the hoppers (where un-roasted pistachios go to the roasters) outside the roaster room
- adding (b) (4) hand sort equipment in the roaster room
- replacing the roaster room walls
- placing drain pipes inside the drains instead of having them divert runoff directly onto the floors areas
- creating a positive air flow system in the roaster and packaging rooms
- placing the dust collecting equipment (formerly observed in the roaster and packaging rooms) outside the building;
- covering the vents and airflow opening in the packaging room
- replacing (b) (4)
- purchasing (b) (4) bins
- maintaining bin cleaning records
- implementing a (b) (4) lb. bin multiple testing program for all incoming raw pistachio products to be analyzed by a private laboratory for *Salmonella*, *Escherichia Coli*, *Shigella*, *Listeria*, Total Plate Count, and Total Coliform with a bin identification (b) (4)
- hiring of consultants for microbiological sampling, processing and document review.
- implementing (b) (4) on its raw finished products
- removing the transfer hopper from the New Building to the raw processing side
- removal of the roller-sorter (sizer) where one of the positive environmentals were detected

The persons responsible for these corrections were H. Lee Cohen, Plant Manager, Setton International Foods, Inc. Commack, New York; General Manager Nicolo (NMI) Lapietra; Jeffrey J. Gibbons, Plant Manager; and Frank G. Aguilera, Quality Supervisor. Mr. Cohen told us of other changes, but these were not listed above since they were not observed on the 4/30/09.

The firm is currently conducting a voluntarily recall of roasted pistachio products and raw kernels (that are not subsequently roasted prior to retail sale) manufactured from September 1, 2008 through March 25, 2009, including the 2007 & 2008 crop years processed during

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that time period, because *Salmonella* was found in environmental swabs and roasted pistachio products collected based on private laboratory and FDA San Francisco District Laboratory analyses (See page 64).

There were three recall announcements by the firm and three separate recall letters (3/30/09, 4/6 or 7/09, & 4/19 & 20/09) were issued to their wholesale customers regarding the firm's recalled pistachio products (See Attachment D-J).

EXHIBITS COLLECTED

1. Handwritten schedule of products run for 3/27/09 (1 page)
2. Copy of United States Standards for Grades of Pistachio Nuts (8 pages)
3. Sign-in sheet of personnel (FDB, FDA and Setton's Management) during the second issuance of the FDA 482 (1 page)
4. Copy of the sign-in sheet of FDA personnel and Setton's management during the issuance of the FDA 482c and 414 Attachment (1 page)
5. Copies of the Setton Pistachio of Terra Bella, Inc.'s State of California corporate papers (8 pages)
6. Copy of Setton's International Foods, Inc. corporate papers indicating that corporation was later dissolved (7 pages)
7. Copy of firm's Attachment A and B of FDA's recall form (3 pages)
8. Copy of recall customer list (5 pages)
9. Copy of expanded recall customer list (10 pages)
10. Copy of expanded recall product list for FDA (3 pages)
11. Copy of the Finished Package Inventory remaining after the recall (4 pages)
12. Copy of Draft Company Letterhead for the recall (4 pages)
13. Copy of Recall Response Form (4 pages)
14. Copy of Recall Summary Record (28 pages)
15. Copy of Hazardous Material Site Map (used as a floor plan of the plant) and plant layout map (2 page)
16. Copies of American Council for Food Safety/ DFA audits 8/31/06, 11/21/06, 5/11/07, 9/20/07, 1/9/08, 6/10/08, 10/2/08, and 1/7/09 (59 pages)
17. Copies of (b) (4) audits (b) (4) and (b) (4) (33 pages)
18. Copy of Setton's third party audits for the last three years (1 page)
19. Copies of records pertaining to FMO/Lot2818C03 LgB-2 (27 pages)
20. Copies of records pertaining to FMO/Lot 3478B14 LgB- 2R (31 pages)
21. Copies of records pertaining to FMO 0418W/M lot 0338 W/M (Kernels) in (b) (4) (9 pages)
22. Copies of records pertaining to FMO 0548B06 Lg-1 21/25 (9 pages)
23. Copies of records pertaining to FMO 0578 W/M Cal R/S (7 pages)
24. Copy of (b) (4) Analytical Report
Date: 10/24/08 of *Salmonella* analyses (20 pages)

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25. Copy of (b) (4) Analytical Report
Date: 10/27/08 of *Salmonella* analyses (7 pages)
26. Copy of (b) (4) Analytical Report
Date: 10/27/08 of *Salmonella* analyses (2 pages)
27. Copy of (b) (4) Analytical Report
Date: 10/28/08 of *Salmonella* analyses (11 pages)
28. Copies of (b) (4) Analytical
Report Date: 10/30/08, 11/6/08, and 11/17/08 of *Salmonella* analyses (10 pages)
29. Copy of (b) (4) Analytical Report
Date: 11/12/08 and 11/17/08 of *Salmonella* analyses (3 pages)
30. Copy of (b) (4) Analytical Report
Date: 1/23/09 of *Salmonella* analyses (10 pages)
31. Copy of (b) (4) Analytical Report
Date: 1/28/09 of *Salmonella* analyses (8 pages)
32. Copy of (b) (4) Analytical Report
Date: 3/17/09 of *Salmonella* analyses (20 pages)
33. Copies of recall press releases of the firm's customer, Kraft Foods (b) (4) (4 pages)
34. Copies of (b) (4) COA's dated 3/27/09 for (b) (4) environmental swabs (17 pages)
35. Copies of (b) (4) COA's dated 3/28/09 for (b) (4) environmental swabs (17 pages)
36. Copies of randomly picked (last August 2008-silo cleaning time) Confined Space Entry Permit records used for silo cleaning (7 pages)
37. Copies of records showing the last dates that the 2007 crop were packaged on the firm's various packaging lines (16 pages)
38. Copy of a production record showing when 2008 crop was first processed (1 page)
39. Copy of recent (b) (4) audit (March 2009) with firm's written corrective actions (5 pages)
40. Copies of invoices and shipping records showing pistachios coming from state of (b) (4) growers for crop years 2007 and 2008 (16 pages)
41. Copy of record showing countries exported to with estimated poundage (1 page)
42. Copy of the firm's Customer List (9 pages)
43. Copy of (b) (4) microbiological analysis for 1/24/06, 12/8/06 & 2/19/08 (30 pages)
44. Copies of records for pistachios shipped to (b) (4) to be hand sorted and later returned to Setton (2 pages)
45. Copy of Certificate of Origin, Generically Modified Organism Statement and Federal, Food, Drug & Cosmetic Act Letter of Guaranty (4 pages)
46. Copy of the firm's products list (2 pages)
47. Copy of FD&C guaranty from (b) (4) (on of the firm's ingredient suppliers) (1 page)
48. Print outs of Setton International Foods, Inc. corporate structure and Setton Pistachio of Terra Bella's facility organizational chart (6 pages)
49. Copies of Setton's tracking log of their copies provided to FDA (14 pages)

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50. Copies of the timeline for the 5 positives *Salmonella* FMO/Lot that the firm had knowledge of (provided by the firm) (5 pages)
51. Copy of 2007^{(b) (4)} Reports for^{(b) (4)} and^{(b) (4)} water with^{(b) (4)} water analysis (11 pages)
52. Copy of firm's HACCP Plans (57 pages)
53. Copies of the following flow charts: Raw Process In-Shell Pistachios, Raw Process Shelled Pistachios, Artificially Raw Open Pistachios, In-Shell Roasted Line, Kernel Roasted Line, Roasted Open Line, Roasted Flavored Pistachios, and Cashew Roasted Line (9 pages)
54. Copy of firm's shared equipment flow charts (7 pages)
55. Copy of Food Allergen Program (9 pages)
56. Copy of Pest Control Program with an example of a randomly-picked pest record (8 pages)
57. Copies of the firm's pistachio byproducts and the byproduct customers (33 pages)
58. Copy of randomly picked Roaster Check Sheets (5 pages)
59. Photographs of large gaps above^{(b) (4)} roaster, exposed conveyor buckets stored outside, un-cleanable cloth-like material in roaster room, gaps on side of warehouse doors, gloves and scrubbing tools left unattended outside and conveyor buckets being washed outside (8 pages)
60. Copy of the cashew roaster's parameters (1 page)
61. Copy of Instructions for the^{(b) (4)} Based Temperature Control manual (8 pages)
62. Copy of operator's manual for the firm's^{(b) (4)} device, not complete (only every other page copied) (12 pages)
63. Copy of randomly-picked records of the environmental^{(b) (4)} checks (7 pages)
64. Copy of a random record showing the firm's revised^{(b) (4)} testing (3 pages)
65. Copies of the firm's Sanitation Schedule, Equipment Cleaning Program, Clean Up Procedure for Packaging Room and Packaging Room in New Building (58 pages)
66. Copy of the Equipment Cleaning Program last updated 3/30/2009 (11 pages)
67. Copies of maintenance records for the^{(b) (4)} and^{(b) (4)} Roasters (32 pages)
68. Copies of the^{(b) (4)} Machine Preventive Maintenance records from 12/13/06 to 3/30/09 (26 pages)
69. Copy of the firm's handwritten descriptions and specifications for the air compressors to the air hoses located at various area throughout packaging and un-roasted processing (1 page)
70. Copy of Setton's Finished Product Sampling Process (2 pages)
71. Copy of a list of Setton's customer's that require microbiological testing on products being shipped to them (1 page)
72. Copy of^{(b) (4)} COA showing results of positive *Salmonella* later determined to be dead DNA (3 pages)

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73. Copy of ^{(b) (4)} *Salmonella* testing procedure, AOAC Official Method 2001.09 (4 pages)
74. Copy of product label for FMO 0588DO5 XLA-2 (4 pages)
75. Copy of spreadsheet provided by the firm of their ^{(b) (4)} microbiological analyses from 12/2004 to 3/19/09 (5 pages)
76. Copies of production and trace back records for FMO/Lot 2407 W/M 28718R-2014 (14 pages)
77. Copies of production and trace back records for FMO/Lot 2507 25828R-2014 (10 pages)
78. Copies of ^{(b) (4)} COA's of the 3 *Salmonella* positive results to finished products collected by Setton during FDA's inspection (3 pages)
79. Copies of the firm's manufacturing code breakdown (4 pages)
80. Copies of the firm's response and related records in response to FACTS complaint SEA-DO 73148 (25 pages)
81. Copy of the firm's recall program (8 pages)
82. Copies of production and trace back records for FMO/Lot ^{(b) (4)} (4 pages)
83. Copies of production and trace back records for FMO/Lot 0588 D05XLA-1 (12 pages)
84. Copies of production and trace back records for FMO/Lot 0588 DO5XLA-2 (37 pages)
85. Copies of processing floor plan with modifications showing the firm's identified shared equipment locations, locations of FDA positive samples, process flow for in-shell and kernels (5 pages)
86. Copies of production and trace back records to FMO 2147 W/M and raw product produced prior to it, invoice, shipping records and the closest sanitation records (19 pages)
87. Copies of production and trace back records to FMO 2948 W/M 29718 R/S - 2018 and 2948 W/M 29728 R/S -2018 and raw product produced prior to it and the closest sanitation records (14 pages)
88. Copies of production and trace back records to FMO 3088 W/M 31128 R/S-2018, 3088 W/M 31218 R/S-2018, 3088 W/M 31518 R/LS-2018 and raw product produced prior to it and the closest sanitation records (17 pages)
89. Copy of the firm's Strategic Plan (12 pages)
90. Master CD-R of photos taken (environmental sub locations & 483 items) taken by FDB for inspection (1 page)
91. Master CD-R of electronic files consisting of bill of ladings for the recall (1 page)
92. Photographs sampled areas or container label of the FDA samples collected that were positive for *Salmonella* (5 pages)
93. Digital photographs take by the firm of different container types and bins (14 pages)
94. Copies of ^{(b) (4)} COAs for 14 finished products tested and submitted by the firm during the inspection (15 pages)

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95. Copies of (b) (4) Analytical Reports for 7 finished products submitted by the firm during the inspection (10 pages)
96. Non-recalled product labels: page 1: Setton Farms Brand Cashews Roasted And Salted Net Wt. 3 oz; page 2: Setton Farms Brand California Almond Raw Shelled 24x16 oz Cello Bags Net Wt. 2 LBS; page 3: Setton Farms Brand California Shelled Almonds Net Wt. 16 oz; page 4: Setton Farms Roasted Salted Cashews Net Wt. 2 LBS; page 5: Roasted And Salted Cashews 24x3 oz Cello Bags Net Wt. 4.5 LBS; page 6: Sunset Valley California Pistachios 21/25 Raw Net Wt. 25 LBS; page 7: California Pistachios Raw 36/40 Net Wt. 25 LBS, California Pistachios Closed Shells Floaters Raw Net Wt. 50 LBS., and California Pistachios Raw Closed Shell Net Wt. 50 LBS; page 8: Sunset Valley Brand California Pistachios Raw 21/25 Net Wt. 50 LBS, California Pistachios Raw 21/25 Net Wt. 50 LBS, and California Pistachios Raw 30/32 Net Wt. 50 LBS; page 9: California Pistachios Raw 21/25 Net Wt. 50 LBS, California Pistachios Raw Closed Shell Sinkers Net Wt. 50 LBS, and California Pistachios Raw 36/40 Net Wt. 50 LBS; page 10: California Pistachios Raw 26/30 Net Wt. 50 LBS and California Pistachios Raw 26/30 US Extra #1 Net Wt. 50 LBS; page 11: California Pistachios Raw 16/18 Net Wt. 1000 LBS and California Pistachios Raw 18/20 Net Wt. 1000 LBS; page 12: California Pistachios Raw 21/25 Net Wt. 1000 LBS and California Pistachios Raw Whole Kernels Net Wt. 1000 LBS; page 13: California Pistachios Raw 16/18 Net Wt. 1900 LBS and California Pistachios Raw 18/20 Net Wt. 1900 LBS; page 14: California Pistachios Raw 21/25 Net Wt. 2000 LBS, California Pistachios Raw 21/25 Net Wt. 2000 LBS, and California Pistachios Raw 21/25 US Extra #1 Net Wt. 2000 LBS; page 15: California Pistachios Raw 16/18 Net Wt. 2000 LBS and California Pistachios Raw 18/20 Net Wt. 2000 LBS; page 16: (b) (4) (b) (4) Brand California Pistachios Raw 21/25 Net Wt. 2000 LBS and California Pistachios Raw 26/30 Net Wt. 2000 LBS; page 17: California Pistachios Raw 18/20 Net Wt. 2100 LBS; page 18: California Pistachios Raw 21/25 Net Wt. 2200 LBS and California Pistachios Raw 26/30 Net Wt. 2200 LBS; page 19: California Pistachios Raw 21/25 Net Wt. 2200 LBS and California Pistachios Raw 21/25 US Extra #1 Net Wt. 2200 LBS; page 20: Pistachio Kernels Raw Halves & Pieces, Raw 18/20 US Extra #1, and Raw Diced Small Kernels; page 21: Pistachio Shelled Raw Split/PCS, Pistachio Kernels Raw Fine Diced, and Raw Pistachios Kernel Pieces (21 pages)
97. Recalled Pistachio Labels: page 1: Setton Farms Brand Roasted Salted Pistachios in Net Wt. 3oz Packages and Shelled Pistachios Roasted/Salted 18 x 9 oz Bags Net Wt. 10.13 LBS.; page 2: California Roasted And Salted 18/20 24x3 oz Cello Bags Net Wt. 4.5 LBS and R/S Mixed Nuts 12x15 oz Produce Tubs; page 3: Sunset Valley Brand California Pistachios Roasted – Salted Net Wt. 10 oz; page 4a: Setton Farms Asian Soy Pistachios Net Wt. 12 oz; page 4b: Setton Farms Brand Hickory Pistachios Net Wt 12 oz; page 5: Setton Farms Brand Garlic Onion Pistachios Net Wt. 12 oz; page 6: Setton Farms Brand Premium California Roasted Salted Pistachios Net Wt. 12 oz; page 7: Setton

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Farms Brand Jalapeno Pistachios Net Wt. 12 oz; page 8: Setton Farms Brand Chili Limon Pistachios Net Wt. 12 oz; page 9: Setton Farms Brand Natural California Pistachios Roasted and Salted 18/20 24x12 oz Cello Bags Net Wt. 18 LBS and Setton Farms Brand Natural California Pistachios Roasted and Salted 18/20 24x16 oz Cello Bags Net Wt. 24 LBS; page 10: Setton Farms Brand Natural California Pistachios Roasted and Salted 18/20 24x12 oz Cello Bags Net Wt. 18 LBS; page 11: Setton Farms Brand Chili Limon Pistachios Net Wt. 14 oz; page 12: Setton Farms Brand Jalapeno Pistachios Net Wt. 14 oz; page 13: Setton Farms Brand Garlic Onion Pistachios Net Wt. 14 oz.; page 14: Setton Farms Brand Roasted and Salted Jalapeno Pistachios 24x14 oz (Stand up Bags) Net Wt. 21 LBS and Setton Farms Brand California Pistachios Roasted and Salted 21/25 Chili Limon 24x14 oz (Stand up Bags) Net Wt. 21 LBS; page 15: Setton Farms Brand Roasted and Salted 21/25 Chili Lemon 24x14 oz (Stand up Bags) Net Wt. 21 LBS and Setton Farms Brand California Pistachios Roasted and Salted 21/25 Hickory 24x14 oz (Stand up Bags) Net Wt. 21 LBS; page 16: Roasted – Salted California Pistachios Net Wt. 14 oz; page 17: Setton Farms Brand Hickory Pistachios Net Wt. 14 oz; page 18: Setton Farms Jalapeno Pistachios Net Wt. 397 g; page 19: Setton Farms Brand Chili Limon Pistachios Net Wt. 397 g; page 20: Setton Farms Brand California Roasted Salted Pistachios Net Wt. 16 oz; page 21: Sunset Valley Brand California Roasted – Salted Pistachios Net Wt. 16 oz; page 22: California Pistachios 18/20 Roasted Light Salt 24x16 oz Cello Bags Net Wt. 24 LBS, Roasted And Salted 18/20 Pistachios 24x1 LB Mesh Bags, and Setton Farms Brand Natural California Pistachios 21/25 24x16 oz. Cello Bags Net Wt. 24 LBS; page 23: (b) (4) Brand California Pistachios R/S 21/25 12x16 oz Bags Net Wt. 12 LBS, Setton Farms Brand R/S 18/20 24x16 oz. Cello Bags Net Wt. 24 LBS, and Roasted and Salted 21/25 24x1 LB Mesh Bags; page 24: Setton Farms Brand California Pistachios 18/20 24x1 LB Craft Bags Net Wt. 24 LBS, Setton Brand California Pistachios Roasted and Salted 18/20 12x1 LB Craft Bags Net Wt, 12 LBS, and Setton Farms Brand Roasted and Salted 21/25 12x1 LB Craft Bags Net Wt. 12 LBS; page 25: (b) (4) Brand In-Shell Pistachios Salted & Roasted Net Wt. 16 oz; page 26: Sam s Choice Brand California Large Pistachios Net Wt. 16 oz; page 27: Setton Farms Brand California Roasted Salted Pistachios Net Wt. 16 oz; page 28: Setton Farms Brand California Pistachios No Salt Net Wt. 16 oz; page 29: Setton Farms Brand California Roasted Salted Pistachios Net Wt. 16 oz.; page 30: Setton Farms Brand California Roasted Salted Pistachios Net Wt. 1 LB; page 31: California Pistachios Roasted & Salted in-shell Net Wt. 16 oz; page 32: (b) (4) Brand Roasted Salted Pistachios Net Wt. 26 oz and Generic Label R/S 21/25 6x26 oz Jars Net Wt. 9.75 LBS; page 33: Setton Farms California Roasted Salted Pistachios Net Wt. 32 oz, page 34: Setton Farms Brand California Pistachios Roasted and Salted 21/25 12x2 LBS Mesh Bag Net Wt. 24 LBS and Setton Farms Brand California Pistachios Roasted and Salted 18/20 12x2 LBS Craft Bags Net Wt. 24 LBS; page 35: (b) (4) Brand Pistachios Roasted Net Wt. 2 LBS; page 36: (b) (4) Brand Pistachios Roasted Net Wt. 2

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LBS; page 37: Setton Farms Brand California Roasted Salted Pistachios Net Wt. 2 LBS; page 38: Setton Farms Brand California Roasted Salted Pistachios Net Wt. 32 oz; page 39: Setton Farms Brand California Roasted salted Pistachios Net Wt. 48 oz; page 40: (b) (4) Brand California Pistachios Net Wt. 64 oz; page 41: Setton Farms Brand California Pistachios Roasted and Salted 18/20 6x5 LBS (Craft Bags) Net Wt. 30 LBS and Setton Farms Brand California Pistachios Roasted and Salted 21/25 6x5 LBS. (Craft Bags) Net Wt. 30 LBS; page 42: Setton Farms Brand California Roasted Salted Pistachios Net Wt. 5 LBS; page 43: (b) (4) Brand Roasted Pistachios Salted Net Wt. 5 LBS; page 44: (b) (4) Brand Roasted Pistachios Salted Net Wt. 5 LBS; page 45: (b) (4) Brand Roasted Pistachios Salted Net Wt. 5 LBS; page 46: Sunset Valley Brand California Pistachios Roasted/Salted 21/25 Net Wt. 25 LBS and Sunset Valley Brand California Pistachios Roasted And Salted 21/25 Net Wt. 25 LBS; page 47: California Pistachios R/S 18/20 Net Wt. 1000LBS, California Pistachios R/S 21/25 Net Wt. 1000 LBS, and California Pistachios Roasted Salted Whole Kernels Net Wt. 1000; page 48: California Pistachios Roasted Salted 21/25 Net Wt. 1700 LBS and California Pistachios Roasted Salted Kernels Net Wt. 1750 LBS; page 49: California Pistachios R/S 21/25 Net Wt. 1800 LBS and California Pistachios R/S 26/30 Net Wt. 1800 LBS; page 50: (b) (4) Brand California Pistachios Roasted Salted 21/25 Net Wt. 2000 LBS and California Pistachios R/S 21/25 Net Wt. 2000 LBS; page 51: Setton Farms Brand Roasted Salted 18/20 U.S. Extra #1 and Setton Farms Brand Roasted Salted 18/20 Fancy; page 52: Roasted And Salted 21/25 U.S. Extra #1 and Roasted Salted 21/25 U.S. Supreme Fancy; and page 53: Roasted And Salted 21/25 U.S. Extra #1 (54 pages total, there are pages 4a & 4b)

ATTACHMENTS

FDA 482's Notice of Inspections

FDA 482c's Notice of Inspections-Request for Records with 414 Attachment

FDA 484's Receipt for Samples

FDA 483 Inspectional Observations

FACTS Samples INV 482178, INV 482179, INV 489157, INV 489158, INV 490162, INV
Collection Report 490163, INV 501599, INV 501600, INV 529672, INV 531954, DOC
501601, DOC 501602, DOC 501603, DOC 501604, DOC 501605, DOC
501606, DOC 501607, DOC 501608, DOC 538400 and DOC 538401

- A. Kraft PowerPoint presentation presented to US FDA concerning positive *Salmonella* pistachios from Setton Farms (8 pages)
- B. Copy of Secretary of State California Business Portal for Setton Pistachio of Terra Bella (1 page)

Establishment Inspection Report

Setton Pistachio of Terra Bella, Inc.

Terra Bella, CA 93270

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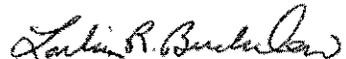
EI End:

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- C. Copy of New York State Department of State Division of Corporations website showing the active status for Setton International Foods of Brooklyn, Inc.
- D. Press Release Announcements on Setton's voluntary recall dated 3/30/09, 4/6/09, and 4/20/09 (6 pages)
- E. Recalled products and customer list for March 30, 2009 voluntary recall (12 pages)
- F. E-mails sent out to customers for March 30, 2009 voluntary recall (28 pages)
- G. Letters sent out to customers for March 30, 2009 voluntary recall (54 pages)
- H. Expanded final customers list of April 7, 2009 voluntary recall (10 pages)
- I. Letter sent out to customers for April 7, 2009 voluntary recall (150 pages)
- J. Example of clarification letter in reference to April 7, 2009 recall sent out to customers on April 19, 2009 (2 pages)
- K. RPM, Section 10-4: Inspection of Food Records (4 pages)
- L. CDPH/FDB News Release dated March 27, 2009 (2 pages)
- M. (b) (4) Product List (1 page)
- N. (b) (4) *Salmonella*- ELFA, AOAC, and PCR testing procedures (18 pages)
- O. Spreadsheet showing Five Positive *Salmonella* Results that Setton Received from Private Laboratories (1 page)
- P. Spreadsheet of Trace back to GNC, Sanfilippo (plus a Costco positive sample) (1 page)
- Q. FACTS SEA-DO Complaint # 73148 (5 pages)
- R. Memorandum regarding photographs taken by FDB during inspection (5 pages)

Establishment Inspection Report
Setton Pistachio of Terra Bella, Inc.
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FEI: 2939582
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