

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

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| DISTRICT ADDRESS AND PHONE NUMBER 1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702 Industry Information: www.fda.gov/oc/industry | DATE(S) OF INSPECTION 03/26/2009 - 04/30/2009* |
| | FEI NUMBER 2939582 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Nicolo (NMI) Lapietra, General Manager

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| FIRM NAME Setton Pistachio of Terra Bella, Inc. | STREET ADDRESS 9370 Road 234, TERRA BELLA |
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| CITY, STATE, ZIP CODE, COUNTRY Terra Bella, CA 93270 | TYPE ESTABLISHMENT INSPECTED Pistachio Manufacturer |
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This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

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 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)(b) (4)(b) (4)(b) (4) number (b) (4)(b) (4) (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)(b) (4)(b) (4) , Invoice number (b) (4)(b) (4)(b) (4) , and (b) (4) number (b) (4) 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)(b) (4)(b) (4)(b) (4) number (b) (4)(b) (4) . 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.

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| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Larkin R. Buckalew, Investigator <i>Larkin R. Buckalew</i> Karen J. Bak, Investigator Estefania Fernandez, Investigator Joanne M. Fukuda, Investigator Terrence Gee, Investigator Helen J. Hamaoka, Investigator <i>Helen J. Hamaoka</i> Alex G. Kalugin, Investigator Jennifer H. Rhyu, Investigator Quynh Strandberg, Investigator Steven M. Galvez, Investigator | DATE ISSUED 04/30/2009 |
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CITY, STATE, ZIP CODE, COUNTRY

Terra Bella, CA 93270

TYPE ESTABLISHMENT INSPECTED

Pistachio Manufacturer

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 observed in the roof of your firm located above the Commercial roaster used to process pistachios (b) (4)(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 Commercial roaster. Thick layers of dust and debris were observed on the red ceiling structures and over head pipes in the packaging room.

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.

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.

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EMPLOYEE(S) SIGNATURE

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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)(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.

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 (b)(4) numbers (b)(4)(b)(4)(b)(4) and (b)(4)(b)(4)(b)(4)(or (b)(4)) were packed on Line (b)(4). The pistachios that ran prior to the aforementioned roasted pistachios were Raw Whole Pistachio Kernels with (b)(4) number (b)(4)(b)(4)(b)(4) 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, (b)(4) number (b)(4) 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 (b)(4) number (b)(4) 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 (b)(4) number (b)(4)(b)(4) In-shell, was positive for *Salmonella*.

On 10/23/08, Roasted/Salted Whole Pistachio Meats with (b)(4)(b)(4)(b)(4)(b)(4) and Roasted/Salted Pistachio Kernels with (b)(4) were processed and packaged on Line (b)(4). Your firm

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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 #8 packaging operation had a buildup of accumulated dust and other debris on the fan blades and fan wire guard.

*** DATES OF INSPECTION:**

03/26/2009(Thu), 03/27/2009(Fri), 03/28/2009(Sat), 03/30/2009(Mon), 03/31/2009(Tue), 04/01/2009(Wed), 04/02/2009(Thu), 04/03/2009(Fri), 04/06/2009(Mon), 04/07/2009(Tue), 04/08/2009(Wed), 04/09/2009(Thu), 04/10/2009(Fri), 04/14/2009(Tue), 04/15/2009(Wed), 04/16/2009(Thu), 04/30/2009(Thu)

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