

May 12, 2009



To: Barbara Cassens  
Food & Drug Administration  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
510-337-6700  
FAX: 510-337-6702

Re: Response to Form FDA 483

Dear Ms. Cassens:

We have received Form FDA 483, dated April 30, 2009, which summarizes the observations made by FDA representatives regarding food safety during their inspection of our facility. Setton Pistachio considers food safety and the wholesomeness of our products of paramount importance, and we are committed to having the highest standards of food safety for our industry.

The purpose of this letter is to inform you that Setton has reviewed and acted upon each of the general observations listed in the FDA form, although some of the specific observations were apparently based on miscommunications and we have provided clarifying information in those instances. In the appendix to this letter, we have listed each observation, followed by a description of, and supporting documentation for, responsive actions taken as well as explanations to correct the record. It is our belief that this information will demonstrate that Setton has been comprehensively responsive to the observations, and that our operations now meet or exceed regulatory requirements.

Let me also note that Setton Pistachio very much appreciates the efforts and guidance provided by the FDA to the pistachio industry as a whole, and to Setton Pistachio in particular. Setton Pistachio is committed to our new focus on food safety and looks forward to continuing to undertake efforts within the pistachio industry regarding best practices which will ensure that the products are safe and wholesome.

I am available to discuss with FDA the steps we have taken, and to respond to any questions or requests for more information.

Sincerely yours,

Lee Cohen

Setton Pistachio of Terra Bella, Inc.

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Below, we provide each of the observations made by FDA representatives along with a description of, and supporting documentation for, corrective actions taken. In some cases, the observations touch upon more than one issue. Where this happens, we have provided breaks separating each issue in the observation, followed by our response to the issue.

## **I. OBSERVATION ONE**

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

**Issue 1:** *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.*

### **Background**

We first wish to note that the positive result for *Salmonella* reported to us in October, 2008, was the first we had received in (b) (4) years of operating history. As a consequence, we, and the pistachio industry as a whole, had not considered *Salmonella* to be a hazard likely to occur, and in the past we acted in good faith to take what we felt were appropriate corrective actions based on this premise. After learning of the initial *Salmonella* positive results, Setton Pistachio hired (b) (4)(b) (4) (also known as the (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)) to perform an extensive environmental risk assessment to determine if there were conditions in our facility which could have contributed to this finding. (b) (4) collected approximately (b) (4) environmental samples throughout the facility to determine whether any pathogens were present. All results were negative. We also expanded our internal environmental testing program, but consistently obtained negative results. Thus, during this period we did not have information to indicate that a modification of our facility environment was needed, despite an extensive third-party risk assessment.

In addition, we (b) (4) the sampling size of our internal product microbial testing program to assist us in identifying any possible sources. Though as noted, several positive *Salmonella* results were reported between October 2008 and March 2009, the results were too sparse and all attempts to identify the origin yielded no data to assist us in tracing them back to a source.

### **Corrective Actions**

We have now completed a comprehensive reassessment of our HACCP plan. The core HACCP plan documents are included in three attachments: (1) ATTACHMENT 1: Process Flow Charts; (2) ATTACHMENT 2: Hazard Analyses; and (3) ATTACHMENT 3: Critical Control Points.



collection of (b) (4)(b) (4) with a maximum allowable number of samples yielding unsatisfactory results for the lot at zero (b) (4). When a (b) (4) plan is implemented, it has a (b) (4) probability of identifying a lot in which the incidence rate of defective material is (b) (4) or greater. The (b) (4) is recognized as an authority in sampling plan design by both the United States Department of Agriculture (USDA) and Food and Drug Administration (FDA).

**Issue 2:** *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.*

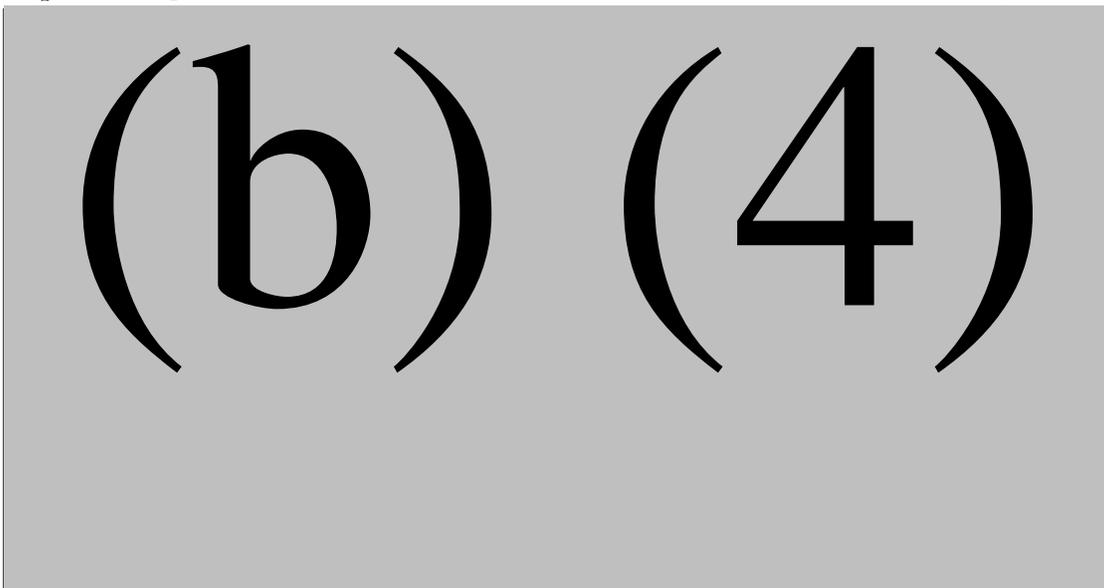
### **Background**

As observed by FDA representatives, there were instances where cross-contamination between raw and roasted pistachios could have occurred. At that time, we did not consider *Salmonella* as a hazard likely to occur, and we did not consider cross-contamination or the use of shared equipment as a possible source.

### **Corrective Actions**

Based on this and other observations made by FDA representatives (see OBSERVATION FOUR below), we now recognize that it is critical to segregate raw materials from post-lethality products. Therefore, we have taken comprehensive steps to ensure complete segregation. As a result, we are now effectively operating (b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) to physically separate production areas. All equipment that (b) (4)(b) (4)(b) (4)(b) (4) is (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) where necessary. (b) (4)(b) (4)(b) (4)(b) (4) to ensure that they are in good shape and readily cleanable.

The specific steps that we have taken include, but are not limited to, the following:



(b) (4)

Additional steps were taken to ensure that the (b) (4) effectively segregates (b) (4) and (b) (4)(b) (4)(b) (4)(b) (4) products. Details are provided below in the response to OBSERVATION THREE.

**Issue 3:** *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)(b) (4)(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 that were sent to other customers.*

### Background

We would like to clarify the circumstances surrounding this order because one might incorrectly infer from the observation that the customer was unaware the product was shipped prior to Setton's receipt of test results. To expedite order fulfillment, the customer had specifically requested that the product be shipped on a "waiver," meaning that the product would be shipped right after sampling but prior to the result being known. The understanding between the parties was that in the unlikely event that the results were positive, the customer would be notified immediately and would return the product to Setton. In this case, when there was a positive result, the pistachios were returned to Setton, washed in (b) (4)(b) (4)(b) (4)(b) (4) an anti-microbial agent), re-roasted and then re-tested as a verification measure. Following the wash step and re-roasting, samples were sent to (b) (4) for salmonella testing. These tests results were negative, and then Setton shipped the re-roasted pistachios, believing that the product had been properly reconditioned. These actions clearly demonstrate Setton's proactive efforts of utilizing (b) (4) kill steps and performing an additional verification test to ensure that only safe, wholesome products reach the consumer.

### Corrective Actions

Our food safety system now comprehensively addresses how to handle product for which positive results have been obtained, and whether identified on the basis of internal or external testing.

First, we have designed a testing and disposition process flow to handle product returned as a consequence of our recall as shown in the process flow charts (included in ATTACHMENT 1). Under this process, all returned recalled product will be subjected to treatment by a validated lethality step. Following treatment, the product will be assigned to (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) sampling plan



samples went to a private laboratory in (b) (4) and the other sample went to a private laboratory in (b) (4)(b) (4). We chose to send this product to separate facilities as a check and balance because it has been stated that despite hundreds of physical environmental tests within our facility we had been, at that point, unable to identify any physical presence of Salmonella.

The results from the (b) (4) laboratory came back negative (b) (4)(b) (4)(b) (4) (b) (4)(b) (4), we released the goods for shipment. After the goods had already departed our facility, we received the results from the (b) (4) laboratory which were positive. We notified our customer who subsequently placed the product on hold and in quarantine where the products remain to this day. No product from this shipment has been or will be used for consumption until properly reconditioned or otherwise handled in accordance with our revised HACCP plan.

We would also like to clarify the observation concerning the circumstances surrounding the product shipped on 3/18/09. Contrary to the FDA observation, this product was never tested. It was ordered by a customer that does not require or request testing as part of their standard customer specification, and none was done. One week after the product was shipped (3/27/09), on our own initiative we performed random testing on inventory in stock which happened to have a similar (b) (4) but which in fact was unrelated to the shipped product. The samples were sent to a third-party private laboratory. The laboratory initially reported negative results on 3/29/09, but then on 4/4/09 the laboratory issued a retraction and revised laboratory report indicating the product was positive (ATTACHMENT 4: (b) (4) Laboratory Report). All products from this (b) (4) and all related production lots are currently on-hold and in quarantine.

Regarding the observation that positive test results were reported from October 28 through March 2009, Setton would like to respectfully bring to FDA's attention that we had halted shipment of all products by 3/26/09 and that the laboratory result was obtained later, but due to the delay caused by the laboratory error, however, the date of the corrected report may have led to the impression that the results applied to a later shipment.

We also wanted to clarify the observation that there were at least eight reported *Salmonella*-positive test results from October 28 through March 2009, Setton would like to respectfully bring to FDA's attention that these did not represent eight independent contamination events. Three of these samples came from the same load, and therefore the number of positive events was five.

### **Corrective Actions**

Our food safety system has undergone a thorough review and has been substantially modified. It contains the quality control elements and planned/systematic procedures for taking all actions necessary to ensure that Setton Pistachios has the ability to produce safe and wholesome products. Thus, we now have in place a food safety system that should be very effective in preventing any undesirable microorganisms of public health significance that are hazards likely to occur on raw pistachios from entering commerce,

through application of microbial interventions, identification and removal of contaminated materials, and establishment of procedures for appropriate responses to positive test results.

As discussed above under OBSERVATION ONE, Issue 1, we have completed a comprehensive reassessment of our HACCP plan. The process flow charts have been revised to accurately reflect our processes (ATTACHMENT 1), the hazard analyses have been redone and now recognize that undesirable microorganisms of public health significance that are hazards likely to occur on raw pistachios include *Salmonella*, (b) (4) (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) ATTACHMENT 2), and we now have (b) (4) CCPs of which (b) (4) directly or indirectly control the undesirable microorganisms of public health significance (ATTACHMENT 3 includes CCP1 – (b) (4) (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) testing, CCP2 – (b) (4)(b) (4)(b) (4)(b) (4)(b) (4) CCP3 – (b) (4)(b) (4)(b) (4)(b) (4) and CCP5 (b) (4)(b) (4)

Our HACCP plan will be continually verified through CCP monitoring and other verification activities. We will also reassess the HACCP plan again at least (b) (4) and whenever necessary including, but not limited to, circumstances such as:

- (1) (b) (4)(b) (4)
- (2) (b) (4)(b) (4)
- (3) (b) (4)(b) (4)
- (4) (b) (4)(b) (4)
- (5) (b) (4)(b) (4)

In addition, we have reassessed and revised our pre-requisite programs. The changes we have made may be summarized as follows:

- (1) (b) (4)
- (2) (b) (4)
- (3) (b) (4)

Setton employees are receiving training in these new SOPs and SSOPs. In addition, Setton is now monitoring worker (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4)(b) (4) with the understanding that these practices play a critical role in minimizing the potential for microbial contamination.

Furthermore, we are implementing a comprehensive and continuous sanitation monitoring program. The purpose is to provide information regarding the effectiveness of the plant's sanitary procedures. In addition, the information will be used to evaluate and continually improve sanitation efforts at our facility.

Setton is also working on implementing vendor and customer certification systems. With respect to vendors, Setton (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) to use (b) (4)(b) (4)(b) (4) and (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) Suppliers of non-pistachio ingredients such as spices will be (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) that the ingredients (b) (4)(b) (4)(b) (4)(b) (4) Setton will (b) (4)(b) (4)(b) (4)(b) (4)(b) (4) comply with these requirements through (b) (4)(b) (4)(b) (4)(b) (4) activity.

Lastly, we have implementing a comprehensively documented Lot track & trace-back process that will identify production lots at the (b) (4) level and then be able to track that lot through (b) (4)(b) (4)(b) (4)(b) (4)(b) (4) until the lot (b) (4)(b) (4)(b) (4)(b) (4) (b) (4). To support this process, Setton has defined a new lot code structure for all production lots under our enhanced food safety focus. A sample of the new lot code structure is as follows:

Sample Revised Lot Code: (b) (4)(b) (4)

Where:



The techniques and methods employed for Setton Pistachio's track and trace program are based upon the experiences of other industries, most notably the (b) (4)(b) (4)

Setton Pistachio has a high degree of confidence that when taken together, all of these elements of our food safety system ensure that we have the ability to produce safe and wholesome products.

**Issue 6:** *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*



.....  
(b) (4)  
.....  
(b) (4)  
.....  
(b) (4)  
.....  
(b) (4)

We also performed a complete deep-cleaning and sanitization of our production facility, employing approximately (b) (4) people during multiple shifts during a period of (b) (4) (b) (4). Cleaning crews were assigned to functional teams and performed the cleaning in

stages in coordination with other teams. The stages included (b) (4)(b) (4)(b) (4) (b) (4)(b) (4) and (b) (4)(b) (4)(b) (4). Standard food-grade cleaning chemicals were used during our sanitation process such as (b) (4)(b) (4) and other approved agents.

## II. OBSERVATION TWO

**Issue 1:** *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.*

### Background

As noted in our response under OBSERVATION ONE, Issue 1, even though we increased the frequency of our product sampling, the results were too sparse in the past to assist us in tracing them back to a source, and we did not check the performance of our roaster.

### Corrective Action

As noted above under Observation One, Issue 1, we are in the process of validating our roasters. The validation process is being performed by a third-party accredited Process Authority (PA) using (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) which were developed by the (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) for almonds. We are also exploring several other intervention processes.

**Issue 2:** *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.*

### Background

As indicated earlier, the positive result for *Salmonella* reported to us in October, 2008, was the first we had received in (b) (4) years of operating history. As a consequence, we did not consider *Salmonella* to be a hazard likely to occur. Therefore, the roaster was not operated as a Critical Control Point and operating parameters were not closely monitored.

### Corrective Actions

As noted previously, roasting is now a CCP (see ATTACHMENT 3). The Critical Limits for this CCP are temperature and time. Setton has installed (b) (4) separate temperature gauges across (b) (4)(b) (4) our dry roasters. In addition, we have installed (b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4)(b) (4) which (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) purposes. Temperature is now monitored using the recently installed temperature gauges

and (b) (4)(b) (4)(b) (4) ], while time is monitored by (b) (4)(b) (4)(b) (4)(b) (4)(b) (4) ]  
The design of the roaster is such that there is a (b) (4)(b) (4)(b) (4)(b) (4)(b) (4) ] and it is  
with this (b) (4)(b) (4) ] that the efficacy of microbial reduction is being validated.

**Issue 3:** *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.*

### **Background**

The circumstances have been discussed previously under OBSERVATION ONE, Issues 3 and 4.

### **Corrective Actions**

As can be seen in the process flow charts for recalled or returned product (ATTACHMENT 1), all such product will be subjected to a lethality treatment and rigorously tested by a high resolution (b) (4)(b) (4)(b) (4) ] sampling plan before being introduced into the processing environment.

In addition, as explained in greater detail below in the response to OBSERVATION FOUR, Setton has now rigorously separated raw and RTE-product streams.

### **III. OBSERVATION THREE**

*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.*

### **Background**

As discussed above, after the positive result for *Salmonella* was reported to us in October, 2008, Setton Pistachio hired (b) (4) ] to perform an environmental risk assessment to determine if there were conditions in our facility which could have contributed to this finding. Despite extensive sampling activity, all results were negative. Thus, during this period we did not have information that indicated a need to evaluate the air flows within our facility.

### **Corrective Actions**

As discussed above in our response to OBSERVATION ONE, Issue 2, Setton has taken extensive steps to segregate raw and post-lethality products. These steps have included the addition of (b) (4)(b) (4) ] the installation of (b) (4)(b) (4)(b) (4)(b) (4) ] and the (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) ] and reduce the potential for cross-contamination. By partitioning spaces, and (b) (4)(b) (4) ] instead of openings, air exchange rates between raw and post-lethality processing areas have been significantly reduced.

In addition to these general steps taken to segregate processing areas, Setton has taken specific steps to improve the air flow system in the facility to prevent cross-contamination including (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)

The effectiveness of these modifications to the plant construction and design will be evaluated on an on-going basis through our new comprehensive and continuous sanitation monitoring program, which includes regular air sampling. Air sampling data will be examined for trends using (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)

#### **IV. OBSERVATION FOUR**

**Issue 1:** *Failure to make 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 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.*

##### **Background**

As discussed previously, there were instances where cross-contamination between raw and roasted pistachios could have occurred. At that time, we did not consider *Salmonella* as a hazard likely to occur, and we did not consider cross-contamination as a possible source.

##### **Corrective Actions**

As discussed above in our response to OBSERVATION ONE, Issue 2, Setton has taken extensive steps to segregate raw and post-lethality products. Raw and roasted pistachios are no longer packed, sorted or processed in the same rooms or on the same equipment. Raw and roasted pistachios now have dedicated equipment including forklifts, bins, conveyor buckets, brooms and sampling carts.

**Issue 2:** *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.*

##### **Background**

As FDA observed, there were intervals between cleanings which seemed to indicate that equipment was not cleaned between flavored pistachio runs. That assumption is not

accurate, however. There were, as a matter of standard operating procedure, cleanings between product runs, but flavored pistachio runs occur infrequently. Therefore, the absence of sanitation documentation for some days merely reflected the fact that no flavored pistachios were run on those days.

### **Corrective Actions**

The allergen program at Setton was reviewed and revised. Employees have been re-trained so as to ensure that documentation is completed indicating that red dye room processing equipment is cleaned and sanitized before and after each flavored pistachio run. Employees are now required to update documentation on a daily basis, including the use of a notation indicating (b) (4)(b) (4) on those days where flavored pistachio runs do not occur so as to provide a contiguous record of sanitation events as compared to flavored pistachio runs (see ATTACHMENT 6: Red Dye Room Sanitation Documentation).

**Issue 3:** *When 14 lots of roasted pistachio records were reviewed, it was determined that 10 of those lots had raw pistachios packed on the same equipment prior to the roasted pistachio being run. Some examples are: [Four examples given]*

### **Background**

As observed by FDA representatives, there were instances where cross-contamination between raw and roasted pistachios could have occurred. At that time, we did not consider *Salmonella* as a hazard likely to occur, and we did not consider cross-contamination as a possible source.

### **Corrective Actions**

As discussed above in our response to OBSERVATION ONE, Issue 2, Setton has taken extensive steps to segregate raw and post-lethality products. Raw and roasted pistachios are no longer packed, sorted or processed in the same rooms or on the same equipment. Raw and roasted pistachios now have dedicated equipment including forklifts, bins, conveyor buckets, brooms and sampling carts. The circumstances documented in the examples of records cited in the FDA observations can no longer occur.

## **V. OBSERVATION FIVE**

*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.*

### **Background**

As indicated earlier, the positive result for *Salmonella* reported to us in October, 2008, was the first we had received in (b) (4)(b) (4) years of operating history. As a consequence, we did

not consider *Salmonella* to be a hazard likely to occur. Therefore, the conveyor buckets were not stored with the degree of care that we now understand to be important.

### **Corrective Actions**

Setton has implemented SSOPs such that raw bins & buckets are cleaned, sanitized and then stored in the raw facility. In a similar manner, RTE bins & buckets are cleaned, sanitized and then stored in the RTE facility. All bins are labeled to distinguish raw from RTE. These actions are documented on a sanitation log (see ATTACHMENT 6: Conveyor Bucket Documentation)..

## **VI. OBSERVATION SIX**

*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.*

### **Background**

As indicated earlier, the positive result for *Salmonella* reported to us in October, 2008, was the first we had received in (b) (4) years of operating history. As a consequence, we did not consider *Salmonella* to be a hazard likely to occur. Therefore, the use of this material was tolerated.

### **Corrective Actions**

The material in question was a funnel. It has been removed and replaced by a new stainless steel drainage funnel. This was part of the extensive program to improve the plant environment discussed under OBSERVATION ONE, Issue 6.

## **VII. OBSERVATION SEVEN**

*Failure to operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating 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.*

### **Background**

As discussed above, after the positive result for *Salmonella* was reported to us in October, 2008, Setton Pistachio hired (b) (4) to perform an environmental risk assessment to determine if there were conditions in our facility which could have contributed to this finding. Despite extensive sampling activity, all results were negative. Thus, during this period we did not have information that indicated a need to clean items such as this portable air circulation fan.

### **Corrective Actions**

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The fan in question was thoroughly cleaned as part of the overall facility sanitation efforts. All portable fans have now been incorporated into an SSOP to ensure that they are cleaned on a regular basis. This was part of the extensive improvements to our food safety system discussed above under OBSERVATION ONE, Issue 5.

 **CONFIDENTIAL**

**ATTACHMENT 1:  
Process Flow Charts**

**ATTACHMENT 2:  
Hazard Analyses**

**ATTACHMENT 3:  
Critical Control Points**

**ATTACHMENT 4:  
Supporting Documentation for Observation #1  
and (b) (4) Laboratory Report**

**ATTACHMENT 5:  
Red Dye Room Sanitation Documentation**

**ATTACHMENT 6:  
Conveyor Bucket Documentation**