



Setton International Foods, Inc

85 Austin Blvd. • Commack, NY 11725
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June 2, 2009

To: Jane Chen
Investigator, Domestic Investigations Branch
Food & Drug Administration
300 Hamilton Ave, Room 309
White Plains, NY 10601

914-682-6166 ext. 11
FAX: 914-682-6170

Re: Response to Form FDA 483

Dear Ms. Chen:

We have received Form FDA 483, dated April 8, 2009, which summarizes the observations made by FDA representatives during their inspection of our facility. Setton International, Inc. 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 International Foods, Inc. has reviewed and acted upon each of the observations listed in the FDA form. In the appendix to this letter, we list each observation followed by a description of, and supporting documentation for, responsive actions taken. It is our belief that this information will be sufficient to assure the FDA that Setton International Foods, Inc. has been comprehensively responsive to the observations, and allow FDA to make a favorable final determination regarding our compliance.

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

Sincerely yours,

A handwritten signature in cursive script that reads "Mia Cohen".

Mia Cohen
Setton International Foods, Inc.



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OBSERVATION ONE

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

Specifically,

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

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

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

Setton International has prepared two new Sanitation Standard Operating Procedures (SSOPs), one directed to the Roasting Department and the other to the Packaging Department (see Attachments 1 and 2).

Use of compressed air has been eliminated in the SSOP for the roaster. The cleaning protocol now calls for all roaster and bin surfaces to be wiped down sequentially with first a solution of food grade quaternary degreaser solution and second a bleach solution containing between (b)(4) ppm of chlorine (see our answer to Observation Two, below). This protocol will be followed end of day (with pre-operational inspection) and with bleach daily between batches of product. End of day cleanup will include pressure washing of the cooling belt. During a (b)(4) procedure the roaster is dismantled, and all parts are power washed including the roasting belt. As the roasting belt is



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continuously passed through hot oil during operations, the risk of microbial contamination is low.

Similar protocols will be used for the blenders and bins in the Packaging Room. Again, use of compressed air has been eliminated, and product contact surfaces in the blender and bins will now be wiped down sequentially with degreaser and bleach solutions daily at end of day (with pre-operational inspection) and with bleach between batches of product.

New monitoring forms have been prepared to accompany these SSOPs, and replace the use of the Master Cleaning Schedule Log. Copies of the monitoring forms are included as Attachment 3.

OBSERVATION TWO

Sanitizing agents are inadequate and unsafe under conditions of use.

Specifically,

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

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

An SSOP for preparing Sanitizing Agents has been prepared (see Attachment 4). It covers the preparation of bleach and quaternary degreaser solutions.

Bleach is to be prepared to contain between (b)(4) ppm of chlorine, which will be checked using chlorine test strips.

OBSERVATION THREE

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



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Specifically,

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

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

A new SSOP was prepared to cover food contact, use of gloves and hand washing procedures (see Attachment 5). This procedure makes it clear that hands are to be washed at a minimum under the following circumstances:

- At the beginning of every work day, after using restroom facilities, after drinking or eating, after smoking, and after every break; employees are required to wash their hands with soap as per the company's hand washing policies.
- Before handling any product, employee must use hand sanitizing stations and put on gloves.
- If gloves are soiled, torn, or otherwise contaminated; gloves must be discarded and hands sanitized before putting on fresh gloves.
- When gloves are discarded after use, hands should be sanitized.

Furthermore, instructions are provided on when to wear, remove or replace gloves.

Employees in all departments of the facility were trained in these proper hand washing procedures on 4/14/09. Supporting training records are provided in Attachment 6.

In addition, a Good Manufacturing Practices monitoring form is being implemented that includes verification that hand washing protocols are being followed (see Attachment 7).

OBSERVATION FOUR

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

Specifically,

The only hand washing sinks in the facility are located in the employee bathrooms. No hand washing sinks were noted in the Packaging Department, Panning Room, Organic



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Room or Roasting Room where ready-to-eat food products are processed and repacked. These processing areas cover approximately 6,400 square feet.

An additional hand sink has been installed in the roasting department with both hot and cold running water, a soap dispenser and a hands free garbage can. During the hand washing training all employees were advised that Setton International expects them to walk to the nearest sink to wash their hands as often as necessary. The GMP Monitoring Form (see Attachment 7) will verify that hand washing protocols are being observed.

OBSERVATION FIVE

Failure to wear hair restraints where appropriate.

Specifically,

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

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

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

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

Training conducted on 4/14/09 included the topic of proper use of hair nets. Supporting training records are provided in Attachment 6. In addition, the GMP Monitoring Form (see Attachment 7) will verify that hair net restraints are being worn in an effective manner.



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OBSERVATION SIX

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

Specifically,

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

The uncovered light was fixed on the same day that it was identified by FDA inspectors, on 4/1/09. The repaired fixture was shown to Mr. Frank Verni, FDA Investigator.

In addition, maintenance personnel have inspected the lighting fixtures and have completed installation of safety shields or safety bulbs throughout the building.