

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

DISTRICT ADDRESS AND PHONE NUMBER

158-15 Liberty Ave.
Jamaica, NY 11433
(718) 340-7000 Fax: (718) 662-5661
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

03/31/2009 - 04/08/2009*

FEI NUMBER

2433583

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mia R. Cohen, Chief Operating Officer

FIRM NAME

Setton International Foods, Inc.

STREET ADDRESS

85 Austin Blvd

CITY, STATE, ZIP CODE, COUNTRY

Commack, NY 11725-5701

TYPE ESTABLISHMENT INSPECTED

Manufacturer and Repacker

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

Specifically,

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

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

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

OBSERVATION 2

Sanitizing agents are inadequate and unsafe under conditions of use.

Specifically,

On 04/02/09, employees were witnessed wiping down both food contact surfaces and non-food contact surfaces of Table # 1 and Table #2 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

EMPLOYEE(S) SIGNATURE

Jane Chen, Investigator *[Signature]* CSO
Frank Verni, Investigator *[Signature]* CSO
Matthew R. Palo, Investigator *[Signature]* CSO
Sarah A. Wangseng, Investigator *[Signature]* CSO

DATE ISSUED

04/08/2009

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sanitizing solution. When tested with a chlorine test strip, concentration was greater than (b) (4) ppm.

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

OBSERVATION 3

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

Specifically,

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

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.

OBSERVATION 4

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

Specifically,

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

OBSERVATION 5

Failure to wear hair restraints where appropriate.

Specifically,

On 03/31/09, an employee with facial hair was observed packing ready to eat veggie chips into plastic containers in the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jane Chen, Investigator Frank Verni, Investigator Matthew R. Palo, Investigator Sarah A. Wangseng, Investigator	04/08/2009

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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 packing ready-to-eat dried berries and chips into plastic containers and the other employee was noted cleaning in the Packaging Department by the bulk packing line.

OBSERVATION 6

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

Specifically,

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

*** DATES OF INSPECTION:**

03/31/2009(Tue), 04/01/2009(Wed), 04/02/2009(Thu), 04/06/2009(Mon), 04/08/2009(Wed)

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EMPLOYEE(S) SIGNATURE

Jane Chen, Investigator *Jane Chen, CSO*
Frank Verni, Investigator *Frank Verni, CSO*
Matthew R. Palo, Investigator *Matthew R. Palo, CSO*
Sarah A. Wangseng, Investigator *Sarah A. Wangseng, CSO*

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