



April 10, 2009

Mr. H. Tom Warwick
District Director
Department of Health and Human Services
P.O. Box 25087
Federal Center, Bldg 20
Denver, Co. 80225-0087

Re: FDA Audit of March 9-10, 2009

Dear Mr. Warwick,

Attached is our response to your Audit, conducted at our facility on March 9-10. We are very appreciative of the professionalism of your staff and the depth of the audit.

The concerns presently surrounding our industry have prompted a number of our customers to request an acknowledgement from FDA that its audit of Sunland has been successfully completed. As indicated in our Audit Response, most of the observations noted were corrected prior to the completion of the audit.

The single positive swab out of the sixty taken, prompted an immediate and thorough cleaning of the source roasting area. The cleaned roasting area was subsequently tested for contamination and found negative.

As indicated by the results we believe we are in full compliance. Please acknowledge the audit successfully closed so we may move forward with our customers.

Sincerely,


Jimmie Shearer
President & CEO

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FDA Audit Response

MARCH 9 – 10, 2009

Date: April 10, 2009

Observation 1

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

- 1) An employee working at the bulk peanut fill line was observed handling the outside of 40 lb finished product buckets and then placing the same gloved fingers on the inside rim of the same buckets as they were being filled with ready to eat Creamy Peanut Butter. A second employee on the same fill line was observed operating the switch and then part placing part of the same hand inside the 40 lb finished product container just prior to their being filled with peanut butter. This is a repeat observation from the last inspection.

❖ **Corrective Action:**

Employees were retrained on the procedure for handling empty bulk containers before the filling line. All employees will have additional training for the proper handling of containers.

Observation 2

All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source.

- 1) The ^{(b) (4)} Filler leaked peanut butter from the pistons and from gaskets on the balance tank creating a source for micro contamination to the finished ready-to-eat peanut butter.

❖ **Corrective Action:**

This pump was cleaned and seals replaced before the closing meeting. (Cleaned: March 9, 2009)

The hand wash sink in the grinder room lacked soap and paper towels. This is a repeat from the last inspection.

❖ Corrective Action:

Plant manager check hand-washing station in grinding room after the closing meeting and found that there was soap and paper towels at the washing station.

2) Product residues were observed on the large (b) (4) mill (used on the (b) (4) as a result of discharging of the pressure relief valve.

❖ Corrective Action:

The (b) (4) mill was cleaned before the closing meeting. (Cleaned: March 9, 2009)

Observation 3

Failure to wear beard covers in an effective manner.

1) Specifically, 1 employee, with a bushy mustache, working on the filling line was not wearing a beard cover. A second employee with a beard and mustache and working on the same line was wearing a beard cover that did not cover his mustache.

❖ Corrective Action:

We are updating procedures to state that all employees with beards and mustaches will have to wear a covering on both beards and mustache.

Observation 4

Employees did not wash/sanitize hands after each absence from the work station.

1) Specifically, 3 employees were observed entering the finished product fill room and working on the fill line without washing their hands.

❖ Corrective Action:

Employees were immediately pulled off the line and retrained on proper hand washing and sanitizing before they were allowed back on the fill line.

Observation 5

Failure to maintain equipment used to hold food ingredients in a manner that protects them from contamination.

1) Specifically, brittle, broken and missing gaskets were observed on the underlids of the salt, sugar, and stabilizer bins.

❖ Corrective Action:

After the closing meeting the gaskets were removed.
