



DEPARTMENT OF HEALTH & HUMAN SERVICES

94491d

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL **RETURN RECEIPT REQUESTED**

January 8, 2004

W/L 19-04

Douglas C. Austin, President
Hi Point Industries, L.L.C.
1811 Mountain Ave.
Norco, CA 91760

Dear Mr. Austin:

The Food and Drug Administration (FDA) conducted an inspection of your food manufacturing facility located at 1811 Mountain Avenue, Norco, California on October 1, 2, 6, 8, and 15, 2003. At the conclusion of the inspection, you were issued a Form FDA-483, List of Inspectional Observations, which delineated a number of insanitary conditions observed in your food manufacturing facility during the inspection. These conditions cause the food products produced in your facility to be adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 402(a)(4), in that they were prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth. You can find the Act through links on the FDA's homepage at www.fda.gov.

The following insanitary conditions were observed by the investigators during the inspection.

1. Employees did not wash or sanitize their hands thoroughly in an adequate handwashing facility at a time when their hands may have become soiled or contaminated [ref. 21 CFR 110.10(b)(3)]. Specifically, an employee in the Packaging Room pushed open the front lid to the trash can to dispose of a container and did not change gloves before continuing to measure and handle dry ingredients that were used in a mixture of cooked egg yolks.
2. Suitable outer garments were not worn that protect against contamination of food and food contact surfaces [ref. 21 CFR 110.10(b)(1)]. Specifically, an employee handled in-process cooked and peeled whole eggs without wearing available plastic protective shields on her forearms. Water accumulated on her forearms and she repeatedly moved her wet forearms over uncovered containers of cooked eggs. Water dripping off the employee's forearm will contaminate the cooked eggs.
3. Hand-washing facilities lacked running water of a suitable temperature [ref. 21 CFR 110.37(e)]. Specifically, on 10/1/03 there was no hot water at the hand-washing facility

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in the hard cook room where cooked eggs were being handled. Lack of suitable temperature water prevents adequate hand washing for employees handling cooked eggs.

4. Food transported by conveyor was not protected from contamination [ref. 21 CFR 110.80(b)(6)]. Specifically, an employee sprayed-cleaned the floor with a hose under the conveyor belt where peeled cooked eggs were being conveyed. Peeled cooked eggs were exposed to the spray of water splashing off the floor.

5. Hand cleaning and sanitizing preparations were not adequate [ref. 21 CFR 110.37(e)(2)]. Specifically, the hand dip in the packaging room where sliced cooked eggs were being handled did not contain any detectable level of sanitizer and egg debris in the hand dip solution was observed when employees were actively handling eggs. Because the hand dip did not contain sanitizer and the debris in the hand dip indicated the hand dip was being used improperly, the employees were handling ready-to-eat eggs with unsanitized hands and gloves.

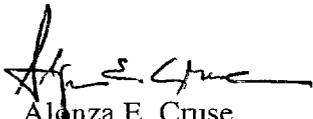
6. All reasonable precautions were not taken to ensure the production procedures did not contribute contamination from any source [ref. 21 CFR 110.80]. Specifically, rather than using a protective plastic sleeve, an employee extended his bare forearm into a water bath containing cooked shell eggs.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office within fifteen (15) working days of the receipt of this letter of the specific steps you have taken to correct the violations noted above, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your written reply should be addressed to the Director of Compliance, U.S. Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612. You may also contact John J. Stamp, Compliance Officer, at (949)608-4464.

Sincerely,



Alonza E. Cruse
District Director

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cc: Jonathan M. Campbell
Hi Point Industries, L.L.C.
1811 Mountain Ave.
Norco, CA 91760

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