



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Los Angeles District
Pacific Region
19900 MacArthur Blvd.
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Irvine, CA 92612-2445
Telephone: 949-798-7600
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WARNING LETTER

February 13, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kevin Valles
Fresh Creative Foods
7559 Mission Gorge
San Diego, CA 92120

W/L 23-03

Dear Mr. Valles:

During an inspection of your firm located at 7559 Mission Gorge, San Diego, California 92120 on August 8-10, 2002, FDA Investigators David G. Whitman and Cori W. Kretschman found that you have serious deviations from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, your seafood and tuna salads are adulterated within the meaning of Section 402(a)(4) of the Act in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You can find this Act and the seafood HACCP regulations through links in the FDA's home page at www.fda.gov. The deviations are as follows:

1. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for "Seafood Spread and Dip" does not list a critical limit at the "mixing & weigh/packing" critical control points to control pathogen growth and toxin formation in the seafood and tuna salads you process. Our investigator observed that your firm stores many of your ingredients at room temperature and those ingredients are processed at room temperature (approximately 70 to 80 degrees F). After your ingredients have been removed from their containers your firm should begin to measure

the time of exposure to unrefrigerated conditions. FDA recommends exposure times (mixing & weigh/pack) be limited to a maximum of two hours under your processing conditions.

Alternatively, if your product is held at internal temperatures above 50°F but not above 70°F, you may increase your maximum exposure time to up to 6 hours. Under these circumstances, time and internal product temperature would be critical limits and should therefore be monitored and recorded.

2. You must have a HACCP plan that at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6 (c) (4). However, your firm's HACCP plan titled "seafood spread and dip" lists a monitoring frequency at the storage critical control point that is not adequate to control pathogen growth. FDA recommends continuous monitoring of storage temperatures for ready-to-eat products. If the product is placed on ice, periodic monitoring of the presence of ice is an adequate means of monitoring temperature. If you choose to monitor cooler temperatures, either a 24-hour high temperature alarm or a temperature data recorder are suggested as appropriate methods. Storage temperatures should be continuously monitored for both your refrigerated ingredients and your finished products.

3. You must implement the recordkeeping system that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the "Receiving" critical control point to control pathogen growth and toxin formation for the surimi used in the seafood salad processed by your firm. Your firm does not record the actual temperatures or visual observations of the refrigerated ingredients, such as surimi, you receive.

Your plan states that you will monitor either visually or take temperatures of incoming ingredients. If the surimi and/or other refrigerated ingredients are less than 4 hours in transit to your plant, the internal temperatures of these products should be monitored. In addition, you should be aware that FDA expects non-seafood ingredients of the seafood salads and tuna salads you process to have the equivalent safeguards included in your HACCP plan to address any hazards associated with them.

4. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points to comply with 21 CFR 123.6 (a) and (c)(2). A critical control point is defined in 21 CFR 123.3(b) as " a point, step, or procedure in a food process at which control can be applied and a food safety hazard can, as a result, be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for "Seafood Spread and Dip" does not list the critical control point of "cooling" to control the food safety hazard of pathogen growth and toxin formation. Your seafood salad and tuna salad are processed at room temperature (between 70 and 80°F). To

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address the hazard of pathogen growth and toxin formation, it is critical that the salads be cooled adequately before shipment. Therefore FDA expects you to assure that the internal temperatures of your salads reach 40° F or below within 4 hours of the weigh/pack step and prior to shipment from your firm.

5. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the condition of cleanliness of food contact surfaces as evidenced by the duct tape on the conveyor belt which cannot be adequately cleaned or sanitized.

This letter may not list all of the deviations in your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110).

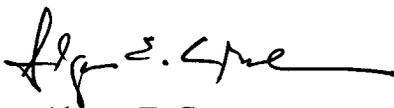
You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

You should take prompt action to correct this deviation. Failure to promptly do so may result in regulatory action without further notice, such as seizure and/or injunction

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. You may wish to include in your response documentation such as HACCP plans, corrective action forms, monitoring forms and recent monitoring data or other useful information that would assist us in evaluating your corrections.

Please send your reply to the Food and Drug Administration, Director, Compliance Branch, 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445. If you have any questions regarding any issue in this letter, please contact MaryLynn Datoc, Compliance Officer at telephone number 949-798-7628.

Sincerely,



Alonza E. Cruse
District Director