



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93148d

WARNING LETTER

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 13, 2002

WL-31-02

Eric H. Lee, Plant Manager/Co-owner
Great River Food
19355 East San Jose Avenue
Industry, CA 91748

Dear Mr. Lee:

We inspected your seafood processing facility, located at 19355 East San Jose Avenue, Industry, CA 91748 on September 26 and 27, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your vacuum-packaged, refrigerated fishery products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, the following deficiencies exist:
 - a) Your firm's HACCP plan for fried fishcakes, fried fish balls, and fried cuttlefish balls does not list the food safety hazard(s) of *Clostridium botulinum*. These products are cooked surimi analogue products that are packaged in vacuum-packages and stored and sold refrigerated. These types of fishery products under such conditions have a potential hazard of *Clostridium botulinum* toxin formation, and controls must be placed in their manufacture to ensure a safe product. Refrigeration alone is not a suitable barrier without adequate temperature controls that include continuous monitoring from processor to consumer. Please refer to FDA's Fish & Fisheries Products Hazards & Controls Guidance: *Third Edition*, Chapter 13 for specific guidance.
 - b) Your firm's HACCP plan for Fish & Cuttlefish Balls/Patties does not list the food safety hazard of allergens. Specifically, your fish cakes and balls contain egg white. Although you list the egg white on your label you must establish a critical control point and monitor your labels to make sure the egg white is listed in the ingredients. Typically, processors establish this critical control point at packaging, receiving or finished product labeling. Information on allergens may be found in Fish & Fisheries Products Hazards & Controls Guidance: *Third Edition*, Chapter 19.

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- c) Your firm also failed to identify pathogen growth and toxin formation as a significant food safety hazard at your cooling after cooking and refrigerated storage process steps. See Chapter 12, Pathogen Growth and Toxin Formation as a Result of Time/Temperature Abuse, in FDA's Fish & Fisheries Products Hazards & Controls Guidance: *Third Edition*.
2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for fried fishcakes, fried fish balls, and fried cuttlefish balls lists a critical limit of [REDACTED] at the "Cooking" critical control point. This is not adequate to control the food safety hazard that you have identified as "Insufficient elimination of preexisting pathogens".

A thermal process used to control pathogen survival through cooking should be based on a scientific study to determine its effectiveness for the intended use. Generally, a minimum time value at your specified temperature is necessary. A cooking temperature alone, [REDACTED] is not adequate.

3. 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 required areas of sanitation with sufficient frequency to ensure control as evidenced by sanitation deficiencies found during our inspection. Employees were observed handling ready-to-eat fishery products prior to packaging after touching insanitary objects without washing and sanitizing their hands.
4. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm maintained sanitation control records that are not adequate. Specifically, your Daily Sanitation Inspection Report (Form P-1) does not include the following sanitation conditions that must be monitored in accordance with 21 CFR 123.11(b): safety of water, condition and cleanliness of food contact surfaces, prevention of cross-contamination, employees health conditions, and exclusion of pests.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as HACCP plans, monitoring forms and recent monitoring data or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at 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

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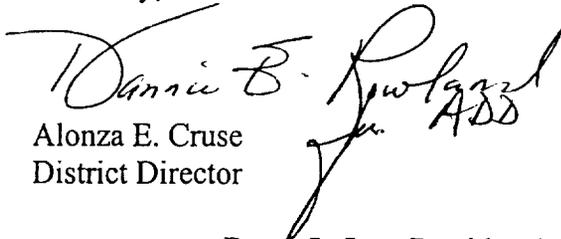
to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

This matter has been assigned to Compliance Officer Robert McNab; any specific questions you may have may be directed to him at phone number 949-798-7709.

Your written reply should be addressed to:

Thomas L. Sawyer, Director, Compliance Branch
U. S. Food and Drug Administration
1990 MacArthur Boulevard, Suite 300
Irvine, California 92612-2445

Sincerely,

A handwritten signature in cursive script, appearing to read "Alonza E. Cruse". The signature is written in dark ink and is positioned above the typed name and title.

Alonza E. Cruse
District Director

cc: Derek L. Lee, President/Co-owner
Great River Food
14500 East Valley Boulevard
City of Industry, CA 91748