



DEPARTMENT OF HEALTH & HUMAN SERVICES

94719d

Public Health Service
Food and Drug Administration
Los Angeles District

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

WARNING LETTER

May 3, 2004

Derek L. Lee, President/Co-owner
Rice Field Corporation
14500 East Valley Blvd.
City of Industry, CA 91748

WL 37-04

Dear Mr. Lee:

We inspected your seafood processing facility, located at 14500 East Valley Blvd., City of Industry, CA 91748 on January 29-February 4, 2004 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, cause your vacuum-packaged, refrigerated fishery products such as "Cooked Fish Balls" and "Fried Cuttlefish Balls" to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the 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 verify that your HACCP plan is adequate to control the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a). However, your firm did not verify that the current HACCP plan for refrigerated, vacuum-packaged ready-to-eat fish balls is adequate to control the food safety hazard of *Clostridium botulinum* survival, growth and toxin formation.

During the inspection, you indicated to our investigator that your current operating parameters (critical limits) at the batch pasteurization critical control point are designed to achieve an internal product temperature of [REDACTED]. You could not, however, show us through scientific studies or other reference documentation how this internal temperature would be sufficient to control *Clostridium botulinum* type E and nonproteolytic types B & F or other pathogens.

2. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations for any of your critical control points to control food safety hazards such as pathogen growth and toxin formation, pathogen survival and metal fragments that are listed in your HACCP plan.

Derek L. Lee – Rice Field Corporation
Page 2

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

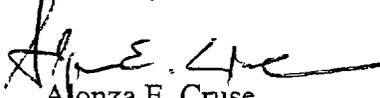
Your written reply should be addressed to:

Pamela Schweikert
Director, Compliance Branch
U. S. Food and Drug Administration
19701 Fairchild
Irvine, California 92612-2445



Additionally, due to the serious nature of the violation noted above and the high-risk nature of your fishery products, we request that you contact this office and schedule a meeting within five (5) days of receipt of this letter at the district office. You may schedule a meeting by calling Mr. Robert B. McNab, Compliance Officer at (949) 608-4409 and arranging a mutually agreeable date and time.

Sincerely,


Alfonza E. Cruse
District Director