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VIA FEDERAL EXPRESS

August 7, 2001

Our Reference: 2920656

James N. Okuhara, President
Okuhara Foods, Inc.
881 North King Street
Honolulu, Hawaii 96817

WARNING LETTER

Dear Mr. Okuhara:

We inspected your seafood processing facility on April 5 and 6, 2001. We conducted this inspection to determine your compliance with FDA's Seafood HACCP regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP and GMP deviations. These deviations cause your refrigerated vacuum packed and/or modified atmosphere packed fish cakes and dried fish to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the deficiencies on a Form FDA 483 and discussed them with you at the conclusion of the inspection. Your serious HACCP and GMP deviations are as follows:

1. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for **Dried Yellowfin Tuna** and **Mackerel** does not list the critical control point (CCP) of In-Process Cooler Storage (after the rinsing step) for controlling histamine formation as a result of

time/temperature abuse. We found in our discussions with management that the salted fish fillets are stored in a cooler for 1-2 days before drying.

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).

(a) However, your firm's HACCP plan for **Dried Yellowfin Tuna Strips** and **Dressed, Split Mackerel** lists:

- (1) A critical limit at the "time and temp management (from thaw to **cooked**)" critical control point that is not adequate to control histamine formation. A delay in the process by placing salted, rinsed, and sliced product in a cooler for 1-2 days before drying the product renders your critical limit of < [REDACTED] hours as monitored by "**time** from thawing to drying" erroneous and is not appropriate for your firm's operation.

Cumulative **time** alone will be exceeded with each batch of product if sliced product is placed in a cooler for periods from overnight to two (2) days before beginning the drying operation. For monitoring purposes, three stages of time/temperature management may be applicable for your operations: a) thawing to in-process cooler storage, b) in-process cooler storage, and c) drying until the internal temperature of the product reaches at least [REDACTED]°F. Assurances should be made that the cumulative exposure to ambient temperatures above 40°F through each of these operations does not exceed 12 hours in the previously frozen fish. The cumulative exposure time above 40°F could be extended to 24 hours in previously frozen fish provided none of that exposure is at ambient temperatures above 70°.

- (2) A critical limit at the "cold storage" critical control point that is not adequate to control pathogen growth. There is no limit on temperature, only that the abuse is to be limited to four (4) hours (extended to [REDACTED] hours via the corrective action listed in the plan).

FDA recommends that product be maintained at 40°F or below throughout refrigerated storage. This can be achieved with a critical limit that limits cooler temperatures to a maximum of 40°F. If the critical limit is exceeded, then the corrective action should take into account the extent of the exposure. Generally,

product exposure times above 70°F should be limited to two (2) hours; product exposure times above 50°F, but not above 70°F, should be limited to six (6) hours; and product exposed to temperatures above and below 70°F should be limited to four (4) hours above 50°F, as long as no more than two (2) of those hours are above 70°F.

(b) However, your firm's HACCP plan for **Broiled Fish Cake (Chikuwa)**, **Deep Fried Fish Cake (Koten and Kushisashi)**, and **Steamed Fish Cake (Uzumaki)** lists time and temperature critical limits at the Cooling CCP that are not adequate to control the hazard of Pathogen Growth. Specifically, from discussions with Mr. Saturo Okuhara and Mr. Dexter Teruya, and based on our observations, we found that after cooking, these products undergo significant handling above 70°F. The recommended time/temperature exposure critical limit is no more than four (4) cumulative hours from the time the product is first significantly handled after cooking to the time the product is packed and stored in the cooler. No more than two of those hours may be above 70°F. (The **cumulative** cooling time should be limited to four (4) hours, not four hours **additional** time below 70°F). You should establish a two-tiered cooling scheme and you should monitor both time and internal product temperature during the cooling operation. Chapter 12 of the Fish & Fishery Products Hazards and Controls Guide can help provide the necessary guidelines.

(c) However, your firm's HACCP plan for MAP, ready-to-eat fishcakes lists a critical limit at the "cold storage" CCP that is not adequate to control pathogen growth. There is no limit on temperature, only that the abuse is limited to four (4) hours (extended to [REDACTED] hours via the corrective action listed in the plan). Refer to item (2)(a)(2) above for the recommended controls that would apply to this issue.

3. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not have HACCP records for **Broiled and Deep Fried Fish Cakes** to document monitoring of the Cooking and Cooling CCPs.

4. You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for **MAP, ready-to-eat fish cakes** lists:

(a) Monitoring procedures at the "Cooking" CCP that are not adequate to control pathogen survival through cooking. A visual check of temperature

and time at the “start of each processing session” is insufficient to insure that the product received the intended cook. In addition to monitoring the start and ending time of each cooking cycle for batch operations and the belt speed or time of exposure at least once per day for continuous cook operation, FDA recommends **continuous** temperature monitoring of critical cook operations with a visual check of the monitoring instrument at least once per batch. In addition to other appropriate records, the temperature recorder chart or digital time/temperature data logger printout should be kept as part of the records for each cook batch or operating period.

(b) A monitoring frequency at the “cold storage” CCP that is not adequate to control pathogen growth. The plan calls for visual thermometer checks of the cooler three (3) times per workday. To control pathogen growth in refrigerated finished product, FDA recommends continuous monitoring of temperature with visual checks of the instrument at least once per day. Temperature recorder charts, digital time/temperature data logger printouts, or storage records showing the results of maximum indicating thermometer checks or high temperature alarm clocks should be kept as part of the monitoring records.

5. You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control pathogen survival when your process for **Steamed Fish Cakes** deviated from the critical limit steaming time of [REDACTED] minutes at the “cooking” CCP. During the April 6, 2001 inspection, we observed an employee steamed a batch of fish cakes for only [REDACTED] minutes. Additionally, your HACCP record for **Steamed Fish Cakes** dated 4/5/01, showed that all batches were only steamed for [REDACTED] minutes.

6. You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a). However, you did not reassess the adequacy of your HACCP plan for the **Deep Fried Fish Cake (Sandwich Fish Cake or Koten)** when tests revealed that your end product water activity exceeded your plan’s maximum of [REDACTED] to control the hazard of pathogen growth (*Clostridium botulinum* toxin formation). Specifically, based on private laboratory analyses of February 14 and 27, 2001, the water activity levels were at [REDACTED]

The moisture content in the raw ingredients, the processing and/or cooking operations, as well as the ingredient formulation, can affect water activity in the final product. In addition to reassessing your processing and cooking critical limits to achieve the appropriate water activity, your firm may want to consider the need for a

receiving critical control point to control the moisture level in your incoming surimi product.

7. 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 following area of sanitation with sufficient frequency to ensure control:

- Protection of food and food contact surfaces from contamination –fans used to cool exposed cooked product, and refrigerator condenser in the finished product cooler were dirty.

We observed similar insanitary conditions at the last inspection of your facility (June 30, and July 3-6, 2000), which was discussed with you at the conclusion of the inspection, and also during the meeting with Compliance Officer Erlinda Figueroa on July 14, 2000. You promised to correct these violations and even provided photos to prove that you made the corrections. Our recent inspection shows that you have failed to implement a corrective action plan to prevent recurrence of these violations, and your firm continues to have insanitary conditions.

We also bring to your attention, which requires immediate follow-up, an observation made during our most recent inspection of your facility. We found that data were being recorded on your Quarterly Thermometer Calibration and Monthly Inspection records prior to the calibration or inspection actually being performed.

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

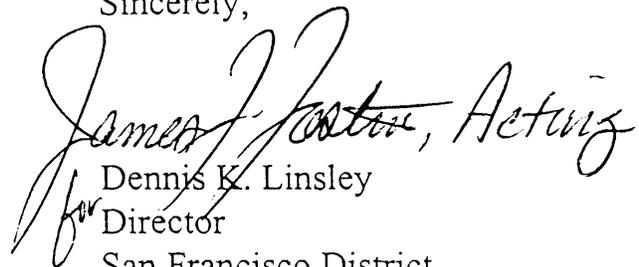
We acknowledge your April 14 and 19, 2001 responses to the inspectional observations presented to you (on a form FDA 483) at the close of the inspection. We also acknowledge Mr. John Kaneko's April 14, 2001 letter. Since you indicate that you have made corrections to those problems, we expect that you will quickly correct the violations addressed in this letter.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response documentation such as time/temperature monitoring records, sanitation records, revised HACCP plans, etc. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

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

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

James J. Linsley, Acting
for
Dennis K. Linsley
Director
San Francisco District