



VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: CFN 2951032

June 3, 2004

Jordan Bow, President
JB5, Inc., dba Royal Hawaiian Seafood
1155 Indiana Street
San Francisco, California 94107

WARNING LETTER

Dear Mr. Bow:

On March 1, 2, and 8, 2004, we inspected your seafood processing facility located at 1155 Indiana Street, San Francisco, California. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulation, 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), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated histamine forming fish, e.g., tuna, Mahi Mahi, Escolar, and your refrigerated, ready-to-eat fish and fishery products, e.g., Dungeness Crab Meat in hermetically sealed containers, canned Pasteurized Blue Crab Meat, and vacuum packaged smoked salmon are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation, and the Food and Drug Administration's (FDA) Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001 through links in FDA's home page at www.fda.gov. We listed the deviations on a Form FDA-483 and

discussed them with you at the conclusion of the inspection. Your serious deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b).

However, your firm does not have HACCP plans for refrigerated, ready-to-eat Dungeness Crab Meat and Pasteurized Blue Crab Meat in hermetically sealed containers, and vacuum packaged smoked salmon to control the food safety hazards of pathogen growth and toxin formation, specifically Clostridium botulinum growth and toxin formation. Your firm has stated that you intend to add these products to an existing HACCP plan. FDA notes that you should conduct a separate hazard analysis for each kind of fish and fishery product. Although you may group kinds of fish and fishery products together or kinds of production methods together, such grouping is only adequate if the food safety hazards, critical control points, critical limits, and procedures are identical for all the fishery products or production methods.

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 for "Tuna (Large), Mahi-Mahi, Sailfish, Wahoo-Ono, Louvar, Sardines, Bonito, Saury, Walu (Escolar)," lists a monitoring procedure and frequency, "Walk-in Cooler Temperature Recording" by "Visual observation of Digital Thermometer" at "Beginning of Operations, 1 hour into Operations, End of Operations" at the Raw Material Storage critical control point that is not adequate to control histamine formation and pathogen growth as a result of time/temperature abuse.

FDA recommends continuous monitoring of the temperatures during storage of histamine forming species and ready-to-eat items, including fresh fish intended for sashimi. Suggested methods to monitor refrigeration include monitoring the cooler

temperature by means of a continuous temperature data recorder with a daily check of the instrument or an alarm system, or monitoring the adequacy of ice or cooling media on the product at least twice a day.

Your firm's HACCP plan for "Tuna (Large), Mahi-Mahi, Sailfish, Wahoo-Ono, Louvar, Sardines, Bonitor, Saury, Walu (Escolar)" lists a monitoring procedure at the receiving critical control point that is not adequate. Specifically, your monitoring procedure at the Receiving critical control point states that "Suppliers guarantee that fish internal temperature does not exceed temperature of 40 degrees throughout shipment." This monitoring procedure is not adequate to control histamine formation.

For secondary processors receiving histamine forming species, FDA recommends that refrigerated fish be received accompanied by transportation records that show that the fish were held at or below 40°F throughout transit or for fish held under ice or cooling media that the product be surrounded by an adequate amount of ice or cooling media at the time of the delivery. The recommended monitoring procedures would be for your firm to monitor the internal temperature of the fish and fishery product throughout transit; or monitor the temperature of the truck or other carrier throughout transportation; or for fish and fishery products with transit times of four hours or less, taking the internal temperature of a representative number of fish and fishery product in the lot at the time of the delivery; or monitor the adequacy of ice or chemical cooling media (it should completely cover the fish) at the time of the delivery. Taking the internal temperature of the fish at delivery, with transit time of over four hours and requiring a supplier's guarantee "that fish temperature does not exceed temperature of 40 degrees Fahrenheit throughout shipment" are not considered an equivalent substitute for any of these procedures.

3. Because you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for "Tuna (Large), Mahi-Mahi, Sailfish, Wahoo-Ono, Louvar, Sardines, Bonito, Saury, Walu (Escolar)" at the Raw Material Storage critical control point, "Adjust thermostat, ice down products," to control histamine

formation and pathogen growth is not adequate because it does not have adequate provisions to ensure that unsafe products do not enter commerce (e.g., discard fish, test for histamine)

FDA took samples during our most recent inspection and tested them for histamine content. Four of the samples had histamine levels exceeding 50 ppm, two of which exceeded 500 ppm. The fish were adulterated under Sections 402(a)(1) and 402(a)(3) of the Act in that they contained histamine, a poisonous or deleterious substance in such quantity as to ordinarily render them injurious to health, and consisted in whole or in part of a decomposed substance. We are aware that you voluntarily destroyed the remaining lot of fish.

Ordinarily, decomposition in fish with these levels of histamine is readily apparent organoleptically. On six occasions, from 1997 through 2003, FDA has discovered decomposed fish held in a storage cooler at your facility. Decomposition in histamine forming species can indicate that the fish have undergone time/temperature abuse and as a result have elevated histamine levels. Failure to refuse or discard histamine forming fish that are decomposed may result in unsafe fish being introduced into commerce by your firm.

You must immediately take appropriate steps to correct the violations. We may take further 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.

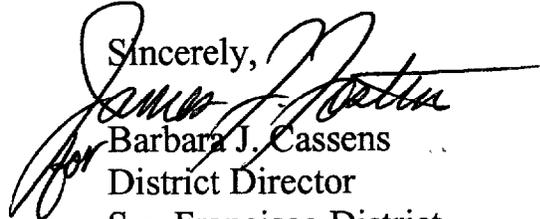
Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of the revised HACCP plan, HACCP monitoring records, 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 Current Good

Manufacturing Practices (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 response should be directed to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,



Barbara J. Cassens
District Director
San Francisco District

cc: Michael Willing, General Manager