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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 25, 1997

Our Reference: 2953449

Glynn Ross, President
Marina Seafoods
74-425 Kealakehe Pkwy
Kailua-Kona, Hawaii 96740

WARNING LETTER

Dear Mr. Ross:

On June 10, 1997, FDA Investigator John Cook, FDA Biologist Linda Cruz, FDA National Sensory Expert James Barnett, and Hawaii Food and Drug Inspector Lynn Wong conducted an inspection of your seafood processing facility at 74-425 Kealakehe Pkwy, Kailua-Kona, Hawaii. The inspection revealed insanitary conditions which constitute violations of the Federal Food, Drug and Cosmetic Act, and related regulations for good manufacturing practices (GMPs) which are established in Title 21, *Code of Federal Regulations*, Part 110 (copy attached).

During the inspection, Biologist Linda Cruz and Sensory Expert James Barnett performed sensory evaluation on a variety of fish that were being held in your refrigerator. Sixteen (16) pieces of fish including shark, mahimahi, and tuna were found decomposed (Class 2 and 3). These fish were adulterated within the meaning of Section 402(a)(3) of the Act, in that they are in whole or in part decomposed. These decomposed fish were ultimately destroyed during the inspection.

At the conclusion of the inspection, FDA presented a list of inspectional observations (Form

FDA 483) to Mr. Clinton Ross, employee. In accordance with your instructions, FDA did not discuss the list of observations with Mr. Clinton Ross. Briefly, the insanitary conditions included: tuna held directly on the refrigerator floor; dirt and blood on the refrigerator floor and storage pallets; a clogged floor drain causing water to back up and flow onto the processing room floor; dirty and heavily scored cutting boards; the presence and storage of old, decomposed fish in the refrigerator (some date tags were 4/21 and 4/23); and the presence and storage of dungeness crabs with signs of severe freezer burns. Other observations not listed on the Form FDA 483 included: fish carcasses covered by dirty plastic tarpaulins; fish intended for bait and chum commingled with fish for human consumption in a crowded and unkempt freezer; headed and gutted thresher shark held directly on the refrigerator floor; and an employee observed scrubbing the skin of a thresher shark with the same push-broom and water he just used to scrub the refrigerator floor.

Foods processed in your facility under these conditions are adulterated within the meaning of Section 402(a)(4) of the Act 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. Adulterated foods are subject to seizure as authorized by Section 304 of the Act. Section 301(a) prohibits the introduction, or delivery for introduction, into interstate commerce of any adulterated and/or misbranded food. Section 301 (c) prohibits the receipt in interstate commerce of any food that is adulterated, and the delivery or proffered delivery thereof for pay or otherwise. The adulteration of food after receipt in interstate commerce is prohibited by Section 301(k).

On June 17, 1997, FDA Investigator John Cook returned to your facility to follow-up on the steps you have implemented to correct the objectionable conditions of your freezer. At this time, Investigator Cook also discussed with you the insanitary conditions listed on the FDA Form 483 issued on June 10, 1997. During this visit, Investigator Cook also noted that the freezer had been cleaned and all fish intended for human consumption had been labeled and segregated from those fish intended for bait. He also noted that the dirty plastic tarpaulins used to cover fish in the refrigerator had been replaced with new ones. However, these corrections are inadequate because they do not address all the insanitary conditions found at your facility. You must immediately take appropriate steps to correct all the violations. Failure to correct the violations may result in legal sanctions such as seizure and/or injunction without further notice.

Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. We request that your response also address

the storage and handling of fresh fish at your firm. Please direct your response to Ms. Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; Fax: 510-337-6707).

Sincerely,

A handwritten signature in cursive script that reads "Patricia C. Ziobro". The signature is written in black ink and is positioned above the printed name and title.

Patricia C. Ziobro
District Director

Attachment: Copy of Title 21, Code of Federal Regulations, Part 110