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CERTIFIED MAIL
RETURN RECEIPT REQUESTEDFood and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751**WARNING LETTER**

FLA-03-25

March 10, 2003

Blanche S. Lee, President
San Carlos Isle Freezer Plant
870 Buttonwood Drive
Fort Myers Beach, Florida 33931

Dear Ms. Lee:

On November 27 and December 2, 2002, we inspected your seafood processing facility, located at the above address. 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) – Fish and Fishery Products. 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 canned pasteurized crab meat, raw fish Tuna, and raw frozen shrimp are adulterated in that these products 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 can find the Act and the seafood HACCP regulation through links in FDA's homepage at <http://www.fda.gov>.

Your deviations are as follows:

Canned Pasteurized Crab Meat

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 a HACCP plan for canned pasteurized crab meat to control the food safety hazards of *Clostridium botulinum* growth/toxin formation and pathogen growth/toxin formation as a result of time/temperature abuse. Your firm currently receives, stores, and distributes refrigerated pasteurized crabmeat, some of which is imported into the United States. FDA currently expects firms to ensure that ready-to-eat products are consistently cooled at safe temperatures during transport to, and storage at, your firm. This may be

done by either continuously monitoring transport and cooler temperatures with a temperature data recorder or by assuring that the goods are completely surrounded by ice or cooling media.

Raw Fish-Tuna

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3(f) as “any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.” However, your firm’s HACCP plan for Raw Fish-Tuna does not list the food safety hazard of Scombrototoxin (histamine) formation at the “Receiving” critical control point (CCP). In your HACCP plan, you have incorrectly identified “Internal Temp.” as the hazard in column #2 at the “Receiving” CCP for this product.

FDA currently recommends that processors, such as yourself, ensure that the histamine producing fish you receive are handled in a safe manner during all times after capture. If you buy your fish directly from the boats, you should ensure that the boats have held the fish in a safe manner. This may be accomplished by taking internal temperatures, conducting sensory examinations for signs of decomposition, and by either requiring Harvest Vessel Records from the fishermen or conducting histamine testing on the fish. If you purchase your histamine producing fish from other processors or brokers, you should ensure that the fish are consistently cooled at safe temperatures during transport to your firm. You should continuously monitor transport and cooler temperatures with a temperature data recorder or by assuring that the goods are completely surrounded in ice or cooling media during those periods. We strongly suggest you refer to Chapter 7 of the Fish and Fisheries Products Hazards and Control Guidance (Third Edition) for specific recommendations for controls, monitoring procedures, and corrective actions.

Raw frozen Shrimp

1. You must implement the recordkeeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the “Weigh/Pack/Label” critical control point to control the hazard of sulfite inclusion listed in your HACCP plan for Raw Frozen Shrimp. Although your firm has the option of choosing where you will control hazards, we suggest that (since all of the shrimp you receive and process are treated with sulfites) you choose to monitor the preprinted labels upon receipt rather than at the packing step.

We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your aforementioned products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. You may wish to include in your response documentation such as amended HACCP plans, revised forms, or other useful information that would assist us in evaluating your corrections. If you are unable to complete all of the 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 of the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have any questions regarding any issue in this letter, please contact Ms. Englund at (407) 475-4741.

Sincerely,


for Emma Singleton
District Director
Florida District Office

cc: Arthur J. Townley, Vice President