DEPARTMENT OF HEALTH & HUMAN SERVICES

94993d

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

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: CFN 2953461/FEI 3000719303

September 24, 2004

Dominic P. Stramaglia, President
Supreme Lobster and Seafood Company
220 E. North Avenue
Villa Park, Illinois 60181

WARNING LETTER

Dear Mr. Stramaglia:

On May 20, 21, and 24, 2004, we inspected your seafood processing facility, Supreme Distributors, Inc. dba Supreme Lobster & Seafood Company, located at 6065 Polaris Avenue, Las Vegas, Nevada. 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; your refrigerated, vacuum packaged raw Scarlet Snapper; your refrigerated, ready-to-eat fish and fishery products, e.g., pasteurized crab meat in hermetically sealed containers and herring in sour cream; and vacuum packaged smoked salmon and trout 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.

Your serious deviations were as follows:

1. You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product that you process, and you must have and implement 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).

   (a) However, your firm does not have a HACCP plan for refrigerated, ready-to-eat pasteurized crab meat in hermetically sealed containers, to control the food safety hazard of pathogen growth and toxin formation, specifically *Clostridium botulinum* toxin formation as a result of time/temperature abuse (i.e., exposure to unsafe temperatures) during refrigerated transport to your facility to be controlled at receiving, at storage, and at any additional critical control points determined by you to be necessary as a result of your hazard analysis.

   (b) Your firm also does not have a HACCP plan for refrigerated, ready-to-eat [redacted] brand Herring in Sour Cream and Snack Bit Herring to control the food safety hazards of pathogen growth and toxin formation, (i.e. *Clostridium botulinum*) and histamine formation associated with exposure to unsafe temperatures during refrigerated transportation to your firm to be controlled at receiving, at storage at your facility and any additional critical control points determined as necessary as a result of your hazard analysis. For your information, FDA does not consider pickling to be an adequate control for the hazard of histamine.

   (c) Your firm does not have a HACCP plan for vacuum packaged raw Scarlet Snapper to control the food safety hazard associated with *Clostridium botulinum* in products during the thawing, storage, and distribution at refrigerated temperatures (i.e., not frozen). Since your firm is thawing frozen Scarlet

Snapper in vacuum packaging, you are creating the potential for the hazard of *Clostridium botulinum* to form, therefore you should provide controls for this hazard. In addition, our investigator observed you thawing the product at temperatures exceeding "refrigeration" (i.e., in standing water at 61°F). These handling conditions are considered unsafe by FDA and should be discontinued immediately. Vacuum packed fresh fish should be thawed at temperatures below 38 degrees F. Chapter 13 of the Fish & Fisheries Products Hazards & Controls Guidance: 3rd Edition provides information regarding appropriate controls, such as the use of time/temperature integrators (TTI). If you prefer to avoid the hazard and the subsequent controls for *Clostridium botulinum*, the product packaging should be opened prior to thawing.

(d) Your firm fails to have a HACCP plan for Refrigerated Vacuum Packed Smoked Fish (Salmon and Trout) to control the food safety hazard of *Clostridium botulinum.* HACCP plans must be specific to a processing location and process, 21 CFR 123.6(b)(1) & (2). The plan your firm obtained via facsimile while our investigator was present applies to another location and does not address all of the necessary critical control points that are associated with your process. Note also that the listed critical limit in this plan (i.e., maximum cooler storage of [redacted]F) is inadequate to control *Clostridium botulinum* growth and toxin formation during refrigerated storage.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at the critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard. However, your firm's HACCP for "Scrombroid Toxin Species" (sic) fails to list a critical limit to control histamine formation in Scombroid species that have been in transit to your facility longer than 4 hours. FDA does not consider monitoring internal temperatures upon arrival as an adequate method of assuring that Scombroid species have been adequately chilled so as to prevent histamine formation throughout transit/shipment. FDA recommends

either monitoring critical limits associated with the adequacy of the cooling media upon receipt or using continuous time/temperature data recorders for the shipping containers or transport vehicle.

3. You must implement the monitoring procedures and recordkeeping system that you have listed in your HACP plan, to comply with 21 CFR 123.6(b). However, your firm did not consistently monitor and record monitoring observations at the Storage critical control point as listed in your HACCP plans for "Scrombroid Toxin Species" (sic). For example, your firm ceased recording daily refrigeration temperatures as of May 1, 2004. We noted during the inspection that your firm monitors refrigeration temperature by means of an alarm system. Since this is one of FDA's recommended methods of monitoring Cooler Storage, we suggest that you update your HACCP plan to reflect this as your current monitoring procedure. In conjunction with the 24 hour alarm system, you should provide some method of assuring that the system is operational on a daily basis.

4. 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,

   (a) Your corrective action plan for "Scrombroid Toxin Species" (sic) to control histamine formation at the Receiving critical control point is not adequate because it does not have provisions to determine product safety and proper disposition of potentially hazardous product. Moreover, there is no information regarding those factors that determine when product will be "refused" as opposed to being placed on "hold for inspection."

   (b) Your corrective action plan for "Scrombroid Toxin Species" (sic) also lists corrective actions at the Storage CCP as follows: "Keep in cooler and ice well" and "Keep frozen or in Cooler." These corrective actions do not have appropriate provisions to determine product safety and proper disposition of potentially hazardous product, and there are no provisions for correction of the cause of the deviation.

(6) You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor key sanitation areas with sufficient frequency to ensure control of:

(a) Safety of water – lack of backflow prevention device on the faucet and/or hose line located under the hand wash sink in the processing room. The hose was connected to the [redacted] cleaner which also had a foamer/degreasing liquid line attached during the cleaning of the seafood processing areas.

(b) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments – crab meat residues observed on the [redacted] band saws used for cutting frozen cooked Dungeness crab.

(c) Maintenance of hand washing, hand sanitizing, and toilet facilities – lack of hand towels and soap in the processing room during processing.

Please be advised that documents collected during our inspection of your facility include information to suggest that some of your fresh fish may be intended for raw consumption as sushi. For example, your HACCP plan for "Scrombroid Toxin Species" (sic) lists "growth of parasites" as a significant hazard. Moreover, sushi grade Ahi Tuna is a product handled by your firm. You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product that you process, and you must have and implement a written HACCP plan for each identified food safety hazard, to comply with 21 CFR 123.6(a) and (b). If your hazard analysis reveals that certain species of fresh fish that you intend to be consumed raw are species that normally have parasites, parasites will be a hazard reasonably likely to occur and you are responsible for having and implementing a HACCP plan that provides controls for this hazard. For more information on the hazard of parasites, please refer to Chapter 5 of FDA's Fish & Fisheries Products Hazards & Controls Guidance: 3rd Edition.

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

Enclosure

cc: Jeffrey M. Franzblau, Executive Vice President
Supreme Distributors, Inc.
6065 South Polaris Avenue
Las Vegas, Nevada 89118