



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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 5, 1997

Our Reference: 2953461

Dominic Stramaglia, President & CEO
Supreme Lobster and Seafood Co.
220 E. North Avenue
P.O. Box 100
Villa Park, Illinois 60181

WARNING LETTER

Dear Mr. Stramaglia:

On July 14, 1997, FDA Investigator Mark Nakano and Nevada Environmental Health Specialist Mary Hahn conducted an inspection of your seafood processing facility at 6065 South Polaris Avenue, Las Vegas, Nevada. The inspection revealed insanitary conditions and poor employee practices which constitute violations of the Federal Food, Drug and Cosmetic Act and related regulations for good manufacturing practices (GMP's), which are established in Title 21, *Code of Federal Regulations*, Part 110 (copy attached). These observations were supported by analytical evidence, which revealed the presence of *Listeria monocytogenes* in one of the environmental swabs taken from the cutting boards.

At the conclusion of the inspection, FDA Investigator Nakano presented a list of inspectional observations (Form FDA 483) to Pat S. Stramaglia, Vice President, and discussed his inspectional observations with him. Attached is a copy for your review and action. Briefly, these conditions included: dirty and heavily scored cutting boards sitting on dirty stainless steel table; fish residue, blood, shell fragments, and dirty water on the processing floors and equipment; fish directly in contact with the dirty standing water on the floor that was about three feet away from a dirty floor drain; fish stored in the processing room insufficiently iced or with no ice; fish held in a cardboard carton with dirty ice; soiled cloth gloves worn by

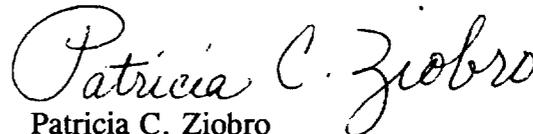
employees and no hair restraints used by them while filleting fish; and garbage containers containing waste materials stored in very close proximity to food contact surfaces.

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. The adulteration of food after receipt in interstate commerce is prohibited by Section 301(k).

We acknowledge that corrective actions had been taken at your firm. However, you must implement appropriate steps to correct these violations on a permanent basis. Failure to properly implement adequate corrections may result in regulatory action without further notice.

Please advise us in writing, within fifteen working days of receipt of this letter, the specific steps you have implemented to prevent recurrence of these violations. Please direct your response to Ms. Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; FAX: 510-337-6707).

Sincerely,



Patricia C. Ziobro
District Director

Attachments: Copy of FDA-483

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

cc VIA CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Pat S. Stramaglia, Vice President
Supreme Lobster and Seafood Co.
6065 South Polaris Avenue
Las Vegas, Nevada 89118