



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

MT782n

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Louis R. Pirilli, Owner
L.P. Wholesale Seafood, Ltd.
295 Midland Avenue
Port Chester, NY 10573

July 21, 1999

Ref: NYK-1999-54

Dear Mr. Pirilli:

On April 6 and 13, 1999, Food and Drug Administration (FDA) Investigator Joseph Milcetic performed an inspection of your seafood processing facility located at 295 Midland Avenue in Port Chester, New York. The inspection was conducted to determine compliance with FDA's seafood processing regulations (Title 21, Code of Federal Regulations (CFR), Part 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110). The inspection revealed that fresh histamine forming species of fish processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. They are adulterated because they were processed and held under conditions contrary to the seafood processing regulations, which constitute insanitary conditions whereby the fish may have been rendered injurious to health.

As we explained in previous letters to your firm, the seafood processing regulations, which became effective December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.

Our inspection revealed serious deviations from the seafood processing regulations that include, but are not limited to, the following:

- Failure to develop and implement a written HACCP plan to address potential food safety hazards associated with seafood products processed by your firm as required by 21 CFR 123.6(b). For example, your firm receives fresh tuna and mahi mahi that pose the species related hazard for scombrototoxin (histamine) formation. For your information, developing a HACCP plan must be performed by an individual who has successfully completed training in the application of seafood HACCP principles or

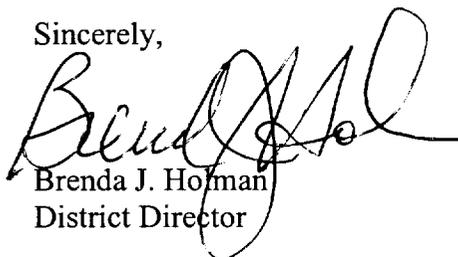
who is otherwise qualified through job experience to perform such function as required by 21 CFR 123.10(a).

- Failure to maintain adequate sanitation control records during processing that document the monitoring of relevant sanitary conditions and practices of your firm and that document correction of any insanitary conditions and practices as required by 21 CFR 123.11(c). The sanitation areas your firm failed to monitor include: conditions and cleanliness of food contact surfaces; prevention of cross contamination; maintenance of hand washing, hand sanitizing, and toilet facilities; protection from adulterants; proper labeling, storage and use of toxic compounds; and control of employees with adverse health conditions.

Neither the above identified violations nor the Inspectional Observations (form FDA 483) given to you at the conclusion of the inspection are intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your firm is in compliance with all of the requirements of the Act and its implementing regulations. You should take prompt action to correct these violations. Failure to achieve prompt corrective action may result in further regulatory action without further notice. These actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days, of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should be directed to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Tel. 718/340-7000 ext. 5507.

Sincerely,



Brenda J. Hoffman
District Director

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cc: HFR-NE1
cc: HFR-NE100
cc: HFR-NE140/QA file
cc: HFR-NE150
cc: HFR-NE1510/E. Jacobson
cc: HFR-NE340
cc: HFS-607
cc: HFI-35/No redaction required
cc: HFA-224
cc: HFC-210 (CFN 2434961)
cc: EF (L.P. Wholesale Seafood, Ltd., CFN 2434961)
cc: warning letter file (NYK-1999-54)
cc: circ./chrono.
cc: BAG

DCB approval 7/21/99
Trak3 No. 1999-1806