



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *g/991d*

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6007

November 7, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Christopher Pinto
President
Sea-Lect Wholesale Seafood Inc.
132 Hulme Street
Mount Holly, New Jersey 08060-2104

File No.: WL 02-NWJ-07

Dear Mr. Pinto

We inspected your firm located at 132 Hulme Street, Mt. Holly, New Jersey, from September 21-25, 2001, and found serious deviations from the seafood hazard analysis and critical control point (HACCP) regulations in Title 21, Code of Federal Regulations (CFR), Part 123. These deviations, some of which were previously brought to your attention, cause your Scombrotoxin-species fish, pasteurized crabmeat, vacuum-packed and smoked fish to be in violation of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations included the following:

1. 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(b). However, your firm does not have a HACCP plan for vacuum-packed sable and kippered salmon, smoked whiting and whitefish, hot-smoked tuna, and pasteurized crabmeat to control the food safety hazard of *Clostridium Botulinum* and other pathogens. This deviation was previously brought to your attention in our letter dated October 17, 2000.

In addition to the lack of a written HACCP plan, your firm failed to implement monitoring procedures and maintain monitoring records for the receipt and/or storage of the above mentioned products to prevent or reduce the associated food safety hazards.

Sea-Lect Wholesale Seafood Inc.
Warning Letter 02-NWJ-07
November 7, 2001

2. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure for determining the adequacy of ice at the Receiving and Storage critical control points for histamine producing fish as listed in your HACCP plan. During the inspection whole tuna and tuna loins were observed not covered or partially covered with ice in Coolers #1, #2, and the product staging area. Also during the inspection, it was revealed that the firm did not perform any monitoring operations upon receipt of histamine-forming fish or thereafter.
3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, there is no documentation to support that the eight key sanitation areas are evaluated and monitored. The key sanitation areas not being monitored include the condition and cleanliness of food contact surfaces, prevention of cross contamination, and hand-washing facilities. For example, cooler fans blowing dirt from ceiling over stored seafood products, employees dipping cloth-gloved hands in hand-dipping stations (plastic tubs) that did not contain a sanitizing agent and an employee performing unsanitary operations without washing and sanitizing hands prior to returning to cutting fish (including ready-to-eat tuna). This deviation was also brought to your attention in our letter dated October 17, 2000.

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 Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug and Cosmetic Act and all applicable regulations.

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 three weeks from your receipt of this letter. Your response should outline the specific steps you have taken to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan, revised monitoring procedures, or other useful information that would assist us in evaluating your corrections. If you cannot complete the corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining deviations.

Sea-Lect Wholesale Seafood Inc.
Warning Letter 02-NWJ-07
November 7, 2001

Please send your reply to the Food and Drug Administration, New Jersey District Office,
10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054, Attn: Rosa L. Brown,
Compliance Technician.

Sincerely,

Edward H. Ellsworth, for
Douglas I. Ellsworth
District Director
New Jersey District