



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region g1979d

Telephone (973)
526-6008

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

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

November 14, 2001

File # 02-NWJ-11

Mr. Julio Pereira
President
Ideal Fish & Seafood Co., Inc.
32 Pacific Street
Newark, NJ 07105

Dear Mr. Pereira:

We inspected your firm, located at 32 Pacific Street, Newark, New Jersey, on September 17, 20, 21, 25, and 28, 2001 and found that you have serious deviations from the seafood hazard analysis critical control point (HACCP) regulations (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your fresh tuna, mahi-mahi, red snapper, vacuum-packed smoked salmon, and pasteurized crabmeat to be in violation of section 402(a)(4) of the Federal Food Drug & 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 were as follows:

1. You must have written HACCP plans to control any food safety hazards that are reasonably likely to occur in order to comply with 21 CFR 123.6(b). However, your firm has no written HACCP plans for the following fish and fisheries products:
 - a. Tuna and other histamine producing species: You must have a written HACCP plan that adequately addresses the food safety hazard of histamine formation for the receipt and storage of Scombrotoxic species fish including, but not limited to tuna, mahi-mahi, and red snapper. This deviation and need for correction, was brought to your attention during our previous inspections on January 27-28, February 1, 1999, and May 4, 6, and 12, 1998.

- b. Canned, pasteurized crabmeat: You must have a HACCP plan that adequately addresses the food safety hazard of *Clostridium botulinum* for the receipt and storage of canned, pasteurized crabmeat.
 - c. Vacuum-packed smoked salmon: You must have a HACCP plan that adequately addresses the food safety hazard of *Clostridium botulinum* for the receipt and storage of vacuum-packed smoked salmon.
2. You have not performed a hazard analysis as required for the receipt and storage of histamine-producing fish, vacuum-packed smoked salmon, and canned pasteurized crabmeat.
 3. You must implement a record-keeping system to comply with 21 CFR 123.6(c)(7). However, your firm cannot assure that cooler #2 storage temperature records for canned, pasteurized crabmeat from May 23, 2001 to September 17, 2001 were filled out when the observations were made.
 - Records indicate that temperatures were taken and recorded on days when your firm was not open or limited in operation. Our investigator has determined that temperatures were filled out for May 27, June 3 and 10, July 4 and 8, August 12, and September 16, 2001, when in fact these were holiday's and/or Sunday's.
 4. You must implement a record-keeping system to comply with 21 CFR 123.6(c)(7). However, your firm cannot assure that cooler #1 storage temperature records for histamine-producing species and vacuum-packed smoked salmon from June 6, 2001 to September 17, 2001 were filled out when the observations were made.
 - Records indicate that temperatures were taken and recorded on days when your firm was not open or limited in operation. Our investigator has determined that temperatures were filled out for June 10, 17, and 24, July 4 and 8, and August 26, 2001, when in fact these were holiday's and/or Sunday's.
 5. Your firm does not have an individual who is adequately trained or qualified by virtue of job experience to develop and reassess your HACCP plan(s), to ensure that corrective actions are taken as needed and to perform record reviews to comply with 21 CFR 123.10. This deviation and need for correction, was brought to your attention during our previous inspections on January 27-28, February 1, 1999, and May 4, 6, and 12, 1998.
 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 *safety of the water that comes in contact with food or food contact surfaces, or is used in the*

manufacture of ice, and maintenance of hand washing, hand sanitizing, and toilet facilities with sufficient frequency as evidenced by:

- Ice-making equipment was rusted and in direct contact with ice used in the storage of seafood products.
 - There was no hot water, soap, or hand drying aids in the employee bathroom.
7. You must implement a written verification procedure outlining written product specifications and affirmative steps for imported products including, but not limited to, anchovy, sardines, horse mackerel, and octopus to ensure that they were processed at the manufacturer to comply with 21 CFR 123.12. This deviation and need for correction, was brought to your attention during our previous inspections on January 27-28, February 1, 1999, and May 4, 6, and 12, 1998.

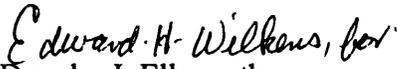
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/ or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries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

Please respond in writing within three weeks from your 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 HACCP plans, copies of receiving and storage monitoring records, sanitation monitoring records, written verification procedures for imported products, 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 the delay and state when the corrections will be completed.

This letter may not list all 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 Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Your response to this letter should be directed to the U.S. Food and Drug Administration, Attention: Anthony M. Criscuolo Jr., Acting Compliance Officer at the address and telephone number listed above.

Sincerely,


Douglas I. Ellsworth
District Director
New Jersey District