



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region g1863d

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**

October 03, 2001

File # 02-NWJ-03

Mr. Frank Bruce Jr.
President
Frank's Fish, Inc.
129 Motts Creek Road
Absecon, NJ 08201

Dear Mr. Bruce:

We inspected your firm, located at 129 Motts Creek Road, Absecon, New Jersey on July 31, 2001 and found that you have serious deviations from the Seafood hazard analysis critical control point (HACCP) regulations found in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your fresh Scombroid species fish products 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. 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. This deviation was previously brought to your attention in our letter of September 8, 1999.

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- b. 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 Scombroid species fish including, but not limited to tuna, shad and mahi-mahi. This deviation was brought to your attention during our previous inspection on July 16, 1999.
2. You must fully implement the record keeping and monitoring system listed in your HACCP plan in order to comply with 21 CFR 123.6(b). Your firm did not record monitoring observations at the receiving or storage critical control points (CCP's) in order to control the hazard of histamine production, as listed in your HACCP plan for fresh bluefish. Although your HACCP plan showed a record keeping system, your firm has failed to perform monitoring activities and to keep any monitoring records for Scombroid species fish since October of 2000. This deviation was brought to your attention during our previous inspection on July 16, 1999.
3. You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR.123.6(c)(3). However, your HACCP Plan for bluefish does not list adequate critical limits at the receiving critical control point. As a primary processor, your receiving critical limit must list one of the following combinations of critical limits to control the hazard of histamine formation:
 - a. Harvest vessel records and sensory evaluation: Your firm may list the obtaining of vessel records for each lot as a means of insuring that histamine-producing species fish have been harvested and stored safely on the harvest vessel. The vessel records would be augmented by sensory evaluation to further insure that histamine- producing fish were safely handled during transit. Additionally, you must take internal temperatures of a representative number of fish per lot at receiving to insure that cool down was properly achieved and that no temperature abuse has taken place while the product was in transit.
 - b. Histamine testing and sensory evaluation: Your firm may choose to list the results of histamine testing against a fixed maximum allowable histamine level coupled with sensory evaluation to establish the level of decomposition in the fish. Additionally, you must take internal temperatures of a representative number of fish per lot at receiving to

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insure that cool down was properly achieved and that no temperature abuse has taken place while the product was in transit.

Note: Please refer to the FDA Fish and Fisheries Product Hazards & Controls Guide, Third Edition, for recommended maximum critical limits, which may vary, based on harvest conditions.

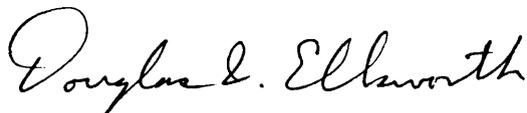
This letter may not list all deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the 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 product(s) and/ or enjoin your firm from operating.

Please respond in writing within three (3) 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 a revised HACCP plan, revised monitoring procedures, copies of revised 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 the delay and state when the corrections will be completed.

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

Sincerely,



Douglas I. Ellsworth
District Director
New Jersey District